

Fig. 2. Illustration of synthetic transobturator midurethral sling placement via (A) the outside-in approach and (B) the inside-out approach. (Courtesy of Mayo Foundation for Medical Education and Research, all rights reserved; with permission.)

formation or systemic disease.^{13–16} In a Swedish nationwide study of 5.4 million women, including 20,905 that underwent midurethral sling placement, having undergone midurethral sling placement was not associated with an increased risk of cancer later in life.¹⁶ Likewise, in review of a New York state registry of 2102 patients undergoing mesh implantation, no increased risk of autoimmune disorders was identified in women that underwent sling placement as compared with a matched control cohort undergoing nonmesh surgery (ie, colonoscopy or hysterectomy).¹⁴

FOOD AND DRUG ADMINISTRATION AND MESH USE

A contemporary discussion of midurethral sling placement is not complete without reviewing the current environment and climate for the use of mesh in pelvic floor surgery.¹⁷ As background, in 2008 the Food and Drug Administration (FDA) released a public notification informing clinicians and patients of adverse events related to use of surgical mesh in pelvic floor surgeries. They noted “serious complications associated with transvaginal placement of surgical mesh in repair of pelvic

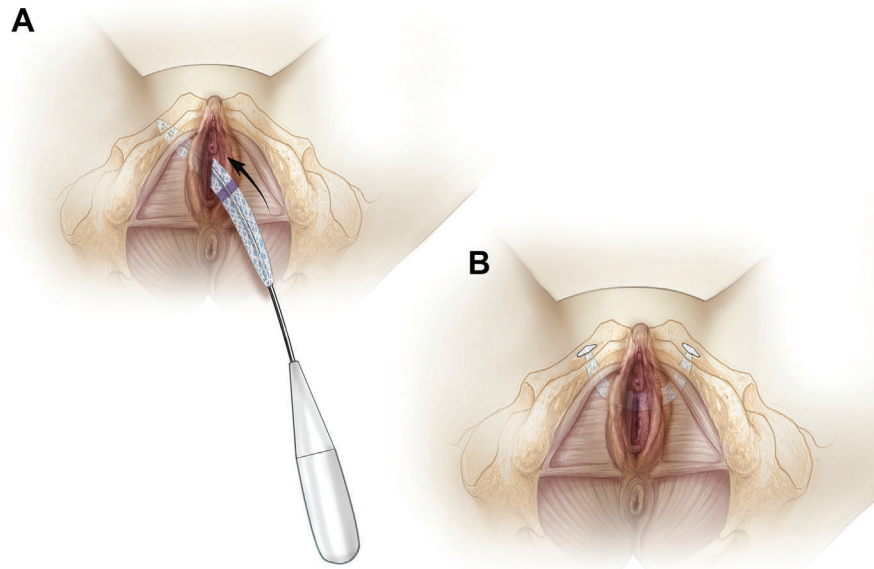


Fig. 3. Illustration of synthetic single-incision sling placement, including: (A) trocar positioning and trajectory (arrow), (B) completed single-incision sling placement. (Courtesy of Mayo Foundation for Medical Education and Research, all rights reserved; with permission.)

organ prolapse and stress urinary incontinence.”¹⁸ Following this, the FDA continued to monitor outcomes for pelvic floor surgeries involving mesh and later issued an update in 2011. In this statement, the FDA noted that risks of serious complications associated with transvaginal pelvic organ prolapse repair with mesh are not rare, and that further updates regarding stress incontinence surgeries would be provided.¹⁹ In 2013, an additional update was released reporting that “the safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to 1 year.”²⁰

Despite this, use of synthetic urethral slings has been subject to dramatically increased scrutiny.¹⁷ Many patients have exposure and preconceived notions regarding mesh placement even before consultation with a pelvic floor surgeon.²¹ For instance, in one study, before consultation with a pelvic floor surgeon 62% of patients reported knowledge of mesh, with the main source of information coming from television advertisements for legal counsel.²¹ Notably, 22% of patients reported that they would not consider implantation of a mesh product. In addition, there was a degree of misinformation, with 28% of patients reporting mesh products had all been recalled.²¹

More recently, in 2016 multiple national subspecialty organizations whose primary focus is the care of women with pelvic floor disorders, including the Society for Urodynamics, Female

Pelvic Medicine, and Reconstructive Surgery and the American Urogynecologic Society, have released a joint position statement supporting the use of synthetic midurethral sling placement in the treatment of women with SUI.⁵ They note that “polypropylene mesh midurethral slings are a standard of care for the surgical treatment of SUI and represent a great advance in the treatment of this condition.”

Likewise, guidelines including comments regarding the safety and efficacy of synthetic midurethral slings exist from the European Urologic Association and AUA.^{12,22} Synthetic midurethral sling placement remains a surgical treatment option for the index female patient with bothersome stress incontinence in the 2017 AUA guideline on the subject (alongside other options, such as autologous fascia pubovaginal sling, Burch colposuspension, and urethral bulking agent injection).²² That being said, with the concerns of vaginal mesh placement for prolapse, synthetic midurethral sling placement has also received increased scrutiny.¹⁷ In one study evaluating the type of slings placed at eight academic centers, over a 7-year period that included the 2011 and 2013 FDA notification, there was a trend toward decreasing use of synthetic mesh slings, although this was not significant.²³ Likewise, there was increased use of autologous fascial slings, although this may represent a referral bias in academic centers.²³

OUTCOMES FOLLOWING SYNTHETIC MIDURETHRAL SLING PLACEMENT

Multi-incision Retropubic and Transobturator Slings

Whether using a transobturator or retropubic approach to multi-incision midurethral sling placement, high-quality evidence exists to support excellent short-term outcomes, with increasing evidence for their long-term efficacy.^{4,24-26} Although there are specific nuances to each approach, such as the complication profiles, medium-term efficacy seems similar.²² Long-term comparative data are less available, although starting to show potentially decreased durability of the transobturator route compared with the retropubic approach.^{25,27,28} Overall, selection of a retropubic approach versus transobturator should be determined based on surgeon comfort and in shared decision making with each individual patient.²²

In short- and medium-term follow-up retropubic and transobturator sling seem to have comparable efficacy.^{4,26,29,30} In a large systematic review and meta-analysis, including 12,113 women in 81 trials, the 1-year subjective cure rates ranged between 62% and 98% for transobturator slings and 71% and 97% for retropubic slings.⁴ Objective cure rates were similar between the two approaches.⁴ In a separate systematic review and meta-analysis including 15,855 women, the retropubic approach was associated with higher subjective (odds ratio, 0.83; $P = .03$) and objective (odds ratio, 0.82; $P = .01$) cure rate compared with the transobturator route.²⁴

With regard to longer term follow-up, the 5-year results of some randomized trials are now available, as is further extended follow-up in retrospective series.^{25,27,31} In the 5-year longitudinal follow-up from the Trial of Mid-Urethral Slings (ToMUS), the retropubic and transobturator groups had a decrease in success rates over time, and the treatments no longer met the prespecified criteria for equivalence, with the retropubic sling showing a slight benefit (51.3% vs 43.4%).²⁵ Likewise, a nationwide Danish study, including 5820 women treated with a midurethral sling, found that the transobturator approach was associated with a two-fold higher risk of reoperation within 5 years compared with the retropubic approach.²⁷

Several smaller cohort studies with extended follow-up to 17 years after retropubic midurethral sling placement are also available.^{32,33} In one prospective series, including 52 women initially, 42 of 46 patients (91%) with an office visit documented were objectively continent at 17-year evaluation.³²

In the other, 90 women underwent surgery and 78% were available for follow-up. Of those, more than 90% were objectively continent, and 87% were subjectively cured or significantly improved.³³

Taken together, the current AUA guideline on the topic notes that physicians may offer either a retropubic or transobturator midurethral sling to an index patient.²²

Single-Incision Transobturator Slings

Single-incision slings are a more recent addition to the surgical armamentarium in treating stress incontinence, and as such data regarding their efficacy are immature.²² Furthermore, the available data are hindered in that many of the early studies evaluated the use of the TVT-Secur, which was later withdrawn from clinical use. For instance, in systematic reviews and meta-analyses evaluating these early studies, the TVT-Secur was found inferior to standard full-length midurethral slings.^{26,34}

More recently, there have been several publications with 1- to 2-year follow-up evaluating the efficacy of other single-incision slings.^{35,36} Over time, modifications to the anchoring mechanism may impact the treatment efficacy. In a recent single center randomized trial of 98 women, at 1-year follow-up there was no significant difference in the rate of a positive cough stress test between the MiniArc single-incision sling and the Monarc sling (29% vs 21%; $P = .5$).³⁵ Likewise, in a single-center randomized trial including 201 women, at the 2-year end point similar cure rates were seen with the Contasure single incision sling compared with the full-length sling.³⁶ The AUA guideline on SUI comments that single-incision sling may be offered to index patients, as long as providers discuss the immaturity of the evidence regarding efficacy and safety with the patient.²²

Situations to Avoid Synthetic Midurethral Sling Placement

There are contraindications to placement of urethral mesh, including patients undergoing concomitant urethral diverticulectomy, urethrovaginal fistula repair, or mesh excision and concomitant SUI surgery.²² This is secondary to potential impact of a foreign body near the suture line impacting healing, which may lead to urethral mesh perforation. Additionally, the recent AUA guideline notes surgeons should consider avoiding mesh placement in patients at risk for poor wound healing (eg, those with prior radiation therapy, local scarring, poor tissue quality),²² and in those taking high-dose systemic corticosteroids. In such settings, other anti-incontinence procedures, such as a pubovaginal sling, urethral bulking

agent injection, or Burch retropubic colposuspension, may remain viable options. Recently, given the risk of voiding dysfunction following autologous pubovaginal sling placement, techniques relying on midurethral positioning of the fascial sling, via a transobturator^{37,38} and a retropubic approach,³⁹ have been reported.

COMPLICATIONS FOLLOWING SYNTHETIC MIDURETHRAL SLING PLACEMENT

As with any procedure, it is important for the surgeon to be aware of and comfortable managing potential surgical complications that may arise. Although we review several specific complications and their management, it is important to contextualize these with their frequency and the overall safety of midurethral sling placement, and recognize that this is not an exhaustive list of all potential complications.^{25,30,40,41} Additionally, it is worth noting that although managed in a similar fashion, the risks of some specific complications vary between the type of sling used (eg, retropubic vs transobturator).^{24,26}

Using a national dataset including 8772 women undergoing isolated midurethral sling placement in the United States, the overall 30-day complication rate was roughly 3.5%, with urinary tract infection the most common adverse event (2.9%).⁴⁰ In this study using the National Surgical Quality Improvement Program dataset, the 30-day readmission rate was 0.9% and the 30-day reoperation rate was 0.7%.⁴⁰ With regard to interventions for mesh-related complications, a population-based cohort from Ontario, Canada including 59,887 women undergoing midurethral sling placement (including concomitant procedures) found that with 10-year follow-up, 3% of women may undergo a procedure for mesh removal or revision.⁴² In this study, lower surgeon volume was associated with a 37% greater risk of complications and repeat mesh-related surgeries.⁴²

Bladder Perforation

Bladder perforation is possible with any route of sling placement, although it is more common with retropubic trocar passage.^{26,30} Universal intraoperative cystoscopy is useful for early identification of bladder perforation, should it occur (Fig. 4). During cystoscopy, adequate bladder distention is needed for appropriate visualization. In addition to evaluating for bladder perforations, cystoscopy at the time of sling may detect other abnormalities, with a reported incidence that 5% of cystoscopies following sling placement had pertinent findings.⁴³

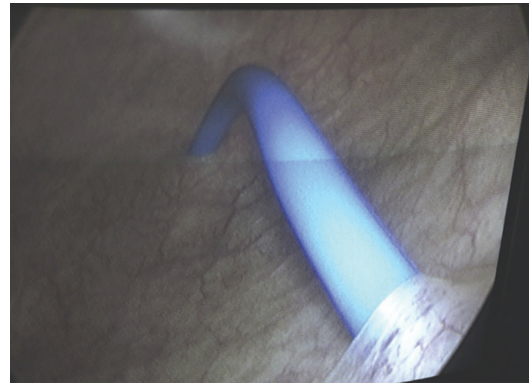


Fig. 4. Intraoperative cystoscopy image showing trocar bladder perforation.

The reported frequency of bladder perforation is variable, from 1% to 34%, and there is some evidence that this rate decreases with increasing surgical experience.⁴⁴ Other potential risk factors for bladder perforation that have been reported include prior cesarean section, colposuspension, body mass index less than 30 kg/m², rectocele, and local anesthesia.⁴⁵

Typically, trocar bladder perforation is managed with removal and repassage of the offending trocar. Postoperative management is variable among surgical practices, ranging from observation to temporary indwelling Foley catheter placement. In one series of 25 patients with bladder perforation, who subsequently passed their voiding trial, and were discharged without a catheter, no significant adverse events were reported.⁴⁶ Others report leaving a catheter in for 1 to several days.⁴⁴ Aside from the potential short-term catheter use, trocar bladder perforation has not been associated with decreased efficacy, or long-term sequela following sling placement in several series.^{43,47} In contrast, one study noted a higher rate of intraoperative trocar perforations among patients that subsequently had a mesh perforation (bladder or urethra) when compared with those with vaginal mesh exposures.⁴⁸ In this study, of the 27 women with postoperative mesh perforations 15 were urethral and 12 involved the bladder, and it is unclear where the area of injury was during trocar placement. Patients with a mesh perforation were also more likely to have a perioperative hematoma or require a blood transfusion.⁴⁸

Urethral Injury

Urethral injury, although rare, is possible during midurethral sling placement, either during the initial dissection or with trocar passage. In these cases, recognition is important to prevent further

complications (such as urethrovaginal fistula or urethral mesh erosion) and allow for appropriate repair. In this setting we repair the urethra primarily using absorbable suture, and delay sling placement.²² A Foley catheter is left in place to facilitate healing, and a repeat attempt at sling placement is performed at a later date.

Vascular Injury

Vascular injury during synthetic midurethral sling placement is a broad category of complications, with severity ranging from a hematoma, which is self-contained and managed with observation, to those necessitating blood transfusion, or even major vascular injury leading to hemodynamic instability. Although vascular injury is possible with all approaches to sling placement, it is more common with retropubic sling placement.^{4,24,26,49,50}

Clinically identified pelvic hematomas have been reported in 0.7% to 8% of women after retropubic midurethral sling placement, and 0% to 2% of women after transobturator sling placement.^{4,51,52} This may be an underestimation of the occurrence rate, because routine imaging to evaluate for this is not typically performed. For instance, in a small prospective series where an MRI was performed 6 to 8 hours after sling placement, hematomas were detected in 25% of patients (6 of 24) undergoing retropubic sling placement (either mesh or porcine dermis).⁵³ Most hematomas involve the retropubic space and can be managed conservatively, with transfusion as needed, if the patient is hemodynamically stable and has adequate symptom control (Fig. 5A, B). It is important to recognize that resolution of the hematoma can take several months, as seen in a study including serial ultrasounds to follow five patients with a retropubic hematoma.⁵¹ In cases of massive hematomas, described as 8 to 12 cm, successful management

via drainage (laparotomy, vaginal, or suprapubic) has been reported.⁵⁴

Intraoperative bleeding from the periurethral connective tissues is typically mild or moderate and is controlled with cautery, suture ligation, or compression (either with a vaginal packing at the end of the case, or slight tension on the Foley catheter, which uses the balloon to help tamponade bleeding).⁵¹ Major vessel injury is rare and necessitates prompt recognition, surgical exploration, and repair.⁵⁵ Some have reported use of endovascular intervention, including embolization in such cases.^{49,56}

Bowel Injury

Bowel perforation is a rare, although potentially life-threatening complication of sling placement, typically when placed via a retropubic approach. Several case reports exist, although the estimated overall incidence is 0.03% to 0.07%.^{4,57–60} It is thought that patients with prior abdominal or pelvic surgery, and those with prior inguinal hernia repair are at increased risk for bowel injury.^{59,61} Potential techniques to decrease the risk of bowel injury include use of Trendelenburg positioning and using a transobturator approach.⁶²

Bowel perforation is a serious potential complication and prompt recognition is crucial. Bowel injury should be suspected in cases of persistent abdominal pain with fever and feculent or purulent drainage from the abdominal sling exit incisions. If suspected, radiographic imaging (either upright abdominal radiograph or computed tomography) should be pursued, with abdominal exploration and management of the bowel injury.

Postoperative Pain

Postoperative discomfort and pain are not uncommon after most surgical procedures, and following

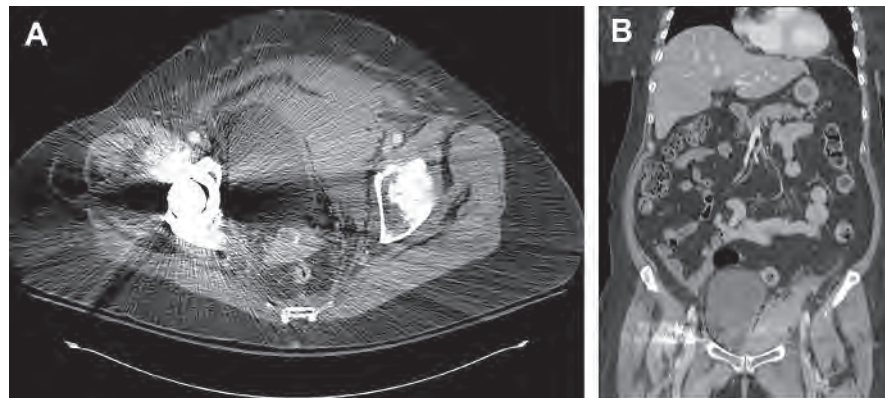


Fig. 5. Retropubic hematoma formation following retropubic sling placement on (A) axial computed tomography imaging and (B) coronal computed tomography imaging.

sling placement is typically self-limited, although persistent pain can occur. In a recent secondary analysis of the ToMUS trial data, the presence of any surgical pain, pain severity, and pain medication use was not different between retropubic and transobturator approaches.⁶³ Overall, 70% of patients were pain-free by 2 weeks after midurethral sling placement, and 90% by 6 weeks.⁶³ Not surprisingly, at 2 weeks, groin pain was more common in the transobturator group and suprapubic pain was more common in the retropubic group.⁶³ At 1 year, 1.7% of patients (5 of 299) in the transobturator group and 1% of patients (3 of 298) patients in the retropubic group reported any pain related to the operation.⁶³ Depending on the severity and duration of the pain, patients may be managed with observation, medical management, pelvic floor physical therapy, and less commonly mesh excision.

Postoperative Voiding Dysfunction

Voiding dysfunction following midurethral sling placement may occur secondary to persistent urinary urgency (which was present preoperatively), de novo urinary urgency, and/or bladder outlet obstruction. Patients with postoperative voiding dysfunction should be assessed for urinary tract infection, and for potential bladder outlet obstruction. If there is no evidence of infection or obstruction, management of persistent urinary urgency follows the clinical principles of over active bladder management.⁶⁴

Patients with slings causing bladder outlet obstruction may present with de novo or worsening urinary urgency, or with elevated postvoid residuals. This is more commonly seen with the retropubic approach midurethral sling placement, as opposed to transobturator approach.^{4,24,26,30} In the ToMUS trial the rate of surgical intervention for voiding dysfunction with 24-month follow-up was 3% for retropubic slings and 0% for transobturator sling.³⁰ Other potential predictors for voiding dysfunction after midurethral sling placement include concomitant prolapse surgery, a lower peak flow rate on unintubated uroflow, voiding by a mechanism other detrusor contraction, and Charlson Comorbidity Index score.^{65–69}

Urinary retention following sling placement most commonly presents as a failed initial voiding trial.⁶⁷ In the early postoperative setting, this is typically managed with bladder drainage (either indwelling Foley catheter, or clean intermittent self-catheterization), with repeat voiding trial. In a multicenter study of 464 isolated sling placements, 21.8% failed the initial voiding trial.⁶⁷ At the follow-up visit, 90% passed a second voiding trial and

38.5% of the remainder passed on the third attempt.⁶⁷ Likewise, in a secondary analysis of the ToMUS trial, the frequency of voiding dysfunction decreased from 20% on postoperative Day 1, to 6% on Day 14, and 2% by 6 weeks.⁷⁰ Similarly, in a population-based cohort, including 18,8454 women, the rate of midurethral sling revision or removal for voiding dysfunction was 1.3%.⁷¹

Variable management of persistent voiding dysfunction has been reported, including continued observation, sling loosening, and sling lysis/partial excision.^{72–74} The optimal timing of surgical intervention is debated. Early sling loosening (up to 10–14 days postoperatively) has been reported, and has the benefit of keeping the original sling intact, with subsequently fewer positive cough stress tests than sling incision.^{72,75,76} The downside of early sling loosening is the potential for overtreatment. For instance, in a small prospective series, 52% of women (11 of 21) needing intermittent catheterization for 7 days or more, and managed with observation, ultimately did not need surgical intervention (ie, sling incision).⁷²

For those managed conservatively that do have persistent symptoms at 4 to 6 weeks, typically sling revision is performed, either in the form of sling lysis or partial sling excision (**Fig. 6**). In these cases, we attempt to limit the extent of periurethral mobilization to preserve sling fixation, which may aid in maintaining continence.^{77,78} It is important to counsel patients that with either technique there is a risk of SUI recurring, which may be severe enough to necessitate undergoing additional treatment, even a repeat anti-incontinence surgery.⁷⁸

Vaginal Mesh Exposure

Vaginal mesh exposure occurs when the mesh material protrudes through the vaginal epithelial lining (**Fig. 7**).⁷⁹ Patients may present with vaginal

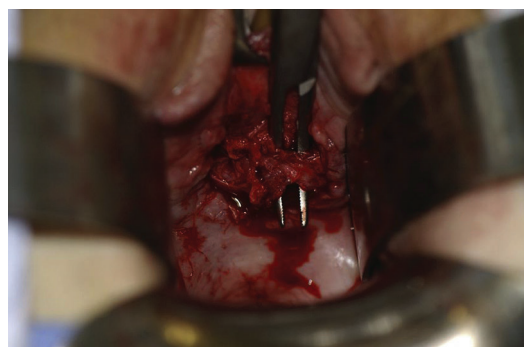


Fig. 6. Sling revision surgery for postoperative voiding dysfunction, a right angle is shown behind the sling following dissection away from the urethra.



Fig. 7. Periurethral vaginal mesh exposure following midurethral sling.

bleeding, discharge, irritation, dyspareunia, or pain for their partner during intercourse. With the use of type I polypropylene mesh materials vaginal mesh exposure is reported to occur in roughly 1.5% to 2% of cases, including long-term follow-up.²⁵ In addition to technical considerations and atrophic vaginal tissues, risk factors for vaginal mesh exposure have been reported including younger age, concomitant prolapse repair, diabetes mellitus, prior bariatric surgery, retropubic approach to sling placement, and preoperative anemia.^{71,80,81}

Management options for vaginal mesh exposure include observation, topical estrogen use, or surgical revision. Observation may be used if the exposure is small and the patient is not symptomatic.

Topical vaginal estrogen has been reported to be successful in cases of small-volume exposures.⁸² Failing more conservative therapy, surgery to revise the mesh may be needed. In these cases, we typically excise a portion of the mesh and reclose the vaginal epithelium over the dissected area. Extensive mesh removal is less commonly needed in cases of vaginal exposure of a type I mesh. In contrast, in patients with a type III mesh in place, complete mesh removal is warranted given the tissue encapsulation that typically occurs (Fig. 8A–C). The more aggressive the mesh revision/removal, the greater the likelihood of recurrent urinary incontinence.

Bladder or Urethral Mesh Perforation/Extrusion

Bladder or urethral mesh erosion may be the result of a missed injury during initial placement, or secondary to true erosion over time. The former of these scenarios highlights the importance of recognizing these injuries at the time of the initial sling, because delayed management has greater morbidity. In cases of intravesical or intraurethral mesh, patients may present with dysuria, urinary tract infections, hematuria, irritative voiding symptoms, or voiding difficulty. On cystoscopy, mesh in the bladder may be directly visible or it may be associated with stone formation (Fig. 9A–C).

The management of mesh in the bladder or urethra involves excision of the mesh and

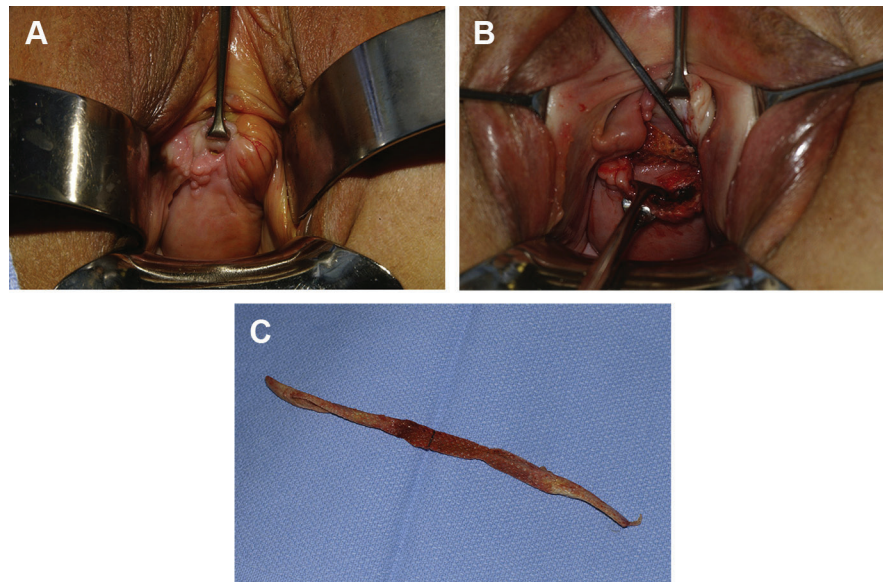


Fig. 8. Vaginal mesh exposure of a type III mesh. (A) a small area of mesh exposure is seen. (B) The tissue response demonstrates encapsulation with minimal tissue ingrowth, as opposed to incorporation seen with type I mesh materials. (C) Completed removal of the entire sling.

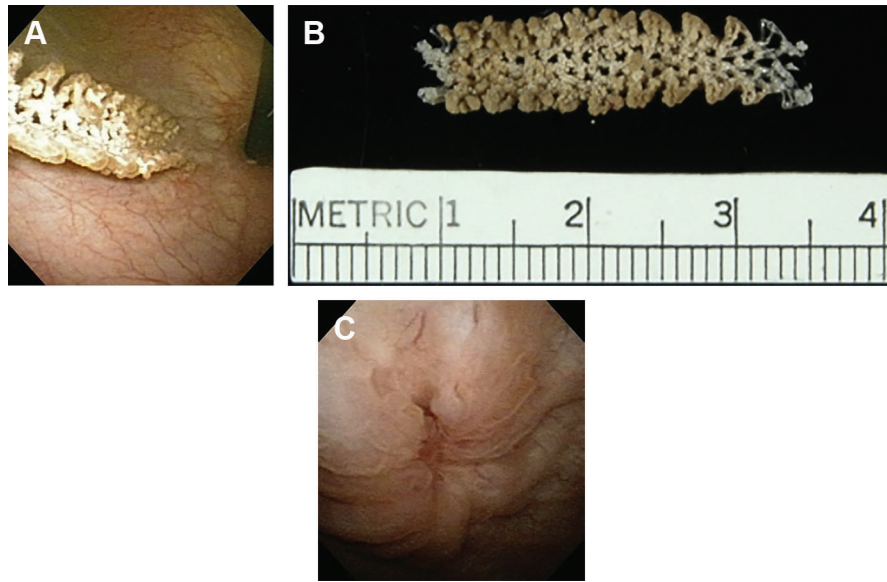


Fig. 9. Bladder perforation by a midurethral sling managed endoscopically with holmium laser excision. (A) Extent of the bladder perforation. (B) Mesh specimen removed following transection with the laser. (C) Bladder on cystoscopy 6-week after the procedure, no residual mesh is identified.

reconstruction. Endoscopic approaches, including use of the holmium laser, have been reported in this setting.^{83–85} Success rates for endoscopic management are higher for midurethral sling mesh in the bladder, rather than the urethra.⁸³ Long-term follow-up is needed to ensure adequate epithelialization over the resection site.⁸⁶ An endoscopic approach avoids the potentially larger morbidity of reconstructive surgery, although likely with somewhat lower long-term success rates. In cases with more severe erosions, failed endoscopic management, concomitant fistula formation, or where the patient prefers a more definitive approach, excision via a transabdominal or transvesical approach with bladder reconstruction or urethroplasty may be necessary.^{87,88} Prospective data following such reconstructions are limited, and one small series ($n = 5$) found that many of the patients continued to have incontinence despite the use of physical therapy/salvage autologous sling placement.⁸⁸

SUMMARY

Synthetic midurethral sling placement is the most studied anti-incontinence procedure available, with multiple randomized trials describing its safety and efficacy, with results out to 5 years. With longer follow-up it seems there may be some benefit in efficacy to retropubic sling placement as compared with the transobturator approach. Single-incision slings are a newer

modification to multi-incision sling placement, and the data regarding safety and efficacy are not as mature as with other forms of sling placement. Complications may occur with the use of synthetic midurethral slings and surgeons performing these should be comfortable with the diagnosis and management of these issues.

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EXHIBIT H

Daniel Steven Elliott, M.D.

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., :Master File No.
PELVIC REPAIR SYSTEM :2:12-MD-0237
PRODUCTS LIABILITY :
LITIGATION :MDL No. 2327

THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN
THE CASES LISTED BELOW :U.S. DISTRICT JUDGE

Mullins, et al. V.	2:12-cv-02952
Ethicon, Inc., et al.	
Sprout, et al. V.	2:12-cv-07924
Ethicon, Inc., et al.	
Iquinto v. Ethicon,	2:12-cv-09765
Inc., et al.	
Daniel, et al. V.	2:13-cv-02565
Ethicon, Inc., et al.	
Dillon, et al. V.	2:13-cv-02919
Ethicon, Inc., et al.	
Webb, et al. V.	2:13-cv-04517
Ethicon, Inc., et al.	
Martinez v. Ethicon,	2:13-cv-04730
Inc., et al.	
McIntyre, et al. V.	2:13-cv-07283
Ethicon, Inc., et al.	
Oxley v. Ethicon,	2:13-cv-10150
Inc., et al.	
Atkins, et al. V.	2:13-cv-11022
Ethicon, Inc., et al.	
Garcia v. Ethicon,	2:13-cv-14355
Inc., et al.	
Lowe v. Ethicon,	2:13-cv-14718
Inc., et al.	
Dameron, et al. V.	2:13-cv-14799
Ethicon, Inc., et al.	
Vanbuskirk, et al. V.	2:13-cv-16183
Ethicon, Inc., et al.	

SEPTEMBER 26, 2015
DANIEL STEVEN ELLIOTT, M.D.

Daniel Steven Elliott, M.D.

Page 2		Page 4	
1	CAPTION CONTINUED:	1	A P P E A R A N C E S
2	Mullens, et al. V. 2:13-cv-16564	2	For the Plaintiffs:
3	Ethicon, Inc., et al. 2:13-cv-17012	3	WAGSTAFF & CARTMELL, LLP
4	Shears, et al. V. 2:13-cv-18479	4	4740 Grand Avenue
5	Ethicon, Inc., et al. 2:13-cv-22606	5	Suite 300
6	Barr, et al. V. 2:13-cv-24393	6	Kansas City, Missouri 64112
7	Ethicon, Inc., et al. 2:13-cv-29260	7	816.701.1100
8	Cook v. Ethicon, Inc. 2:13-cv-29918	8	tcartmell@wcllp.com
9	Stevens v. Ethicon, Inc., et al. 2:13-cv-31818	9	BY: THOMAS P. CARTMELL
10	Harmon v. Ethicon, Inc. 2:13-cv-31881	10	For the Defendants:
11	Snodgrass v. Ethicon, Inc., et al. 2:13-cv-32627	11	BUTLER SNOW, LLP
12	Miller v. Ethicon, Inc. 2:14-cv-09195	12	500 Office Center Drive
13	Matney, et al. V. 2:14-cv-09517	13	Suite 400
14	Ethicon, Inc., et al. 2:14-cv-10640	14	Fort Washington, Pennsylvania 19034
15	Humbert v. Ethicon, Inc., et al. 2:14-cv-12756	15	267.513.1885
16	Gillum, et al. V. 2:14-cv-13023	16	Burt.Snell@butlersnow.com
17	Whisner, et al. V. 2:14-cv-14664	17	BY: NILS B. (BURT) SNELL
18	Ethicon, Inc., et al. 2:14-cv-16061	18	and
19	Tyler, et al. V. 2:14-cv-19110	19	BUTLER SNOW, LLP
20	Kelly, et al. V. 2:14-cv-22079	20	1020 Highland Colony Parkway
21	Ethicon, Inc., et al. 2:14-cv-24911	21	Suite 1400
22	Lundell v. Ethicon, Inc., et al. 2:14-cv-24999	22	Ridgeland, Mississippi 39157
23	Cheshire, et al. V. 2:14-cv-28620	23	601.948.5711
24	Burgoyne, et al., V. 2:14-cv-29624	24	paul.rosenblatt@butlersnow.com
25	Bennett, et al., V. 2:14-cv-29624	25	BY: PAUL S. ROSENBLATT
25	Ethicon, Inc., et al.		

Page 3		Page 5	
1	DEPOSITION OF DANIEL STEVEN ELLIOTT, M.D.,	1	I N D E X
2	produced, sworn and examined on behalf of the	2	WITNESS: DANIEL STEVEN ELLIOTT, M.D.
3	Defendants, pursuant to Notice and Agreement, on	3	Examination by Mr. Snell 9, 326
4	Saturday, the 26th day of September, 2015, between the	4	Examination by Mr. Cartmell 323
5	hours of 9:41 a.m. and 5:54 p.m. of that day, at the	5	
6	law offices of Wagstaff & Cartmell, LLP, 4740 Grand	6	EXHIBITS
7	Avenue, in the City of Kansas City, in the County of	7	NUMBER DESCRIPTION PAGE
8	Jackson, and the State of Missouri, before me,	8	Exhibit 1 - Amended notice of Deposition of 9
9	NAOLA C. VAUGHN, CCR No. 1052, CRR, RPR, a Certified	9	Daniel Elliott, M.D.
10	Court Reporter, within and for the States of Missouri	10	Exhibit 2 - Updated publication list 11
11	and Kansas.	11	Exhibit 3 - International Journal of Urology 11
12		12	Long-term quality of life outcomes
13		13	and retreatment rates after robotic
14		14	sacrocolpopexy
15		15	Exhibit 4 - The Cochrane Collaboration 54
16		16	Mid-urethral sling operations for
17		17	stress urinary incontinence in women
18		18	Exhibit 5 - Oxford Level of Evidence Pyramid 60
19		19	Exhibit 6 - International Urogynecology Journal 66
20		20	Long-Term (10-15 years) Follow-up
21		21	after Burch Colposuspension for
22		22	Urinary Stress Incontinence
23		23	Exhibit 7 - Cochrane Database Syst Rev 2015 89
24		24	(Dr. Elliott's copy)
25		25	

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Daniel Steven Elliott, M.D.

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1	EXHIBITS (Continued)		1	EXHIBITS (Continued)	
2	NUMBER	PAGE	2	NUMBER	PAGE
3	Exhibit 8 - American Urological Association	116	3	Exhibit 22 - In-Depth Nano-Investigation of	250
4	AUA Position Statement on the Use		4	Vaginal Mesh and Tape Fiber	
5	of Vaginal Mesh for The Surgical		5	Explants in Women	
6	Treatment of Stress Urinary		6	Exhibit 23 - FDA article on Medical Devices,	264
7	Incontinence		7	Considerations about Surgical Mesh	
8	Exhibit 9 - IUGA Position Statement on	134	8	for SUI	
9	Mid-Urethral Slings for Stress		9	Exhibit 24 - Journal of Urology, Time Dependent	289
10	Urinary Incontinence		10	Variations in Biomechanical Properties	
11	Exhibit 10 - AUGS/SUFU Position Statement on	139	11	of Cadaveric Fascia, Porcine Dermis,	
12	Mesh Midurethral Slings for Stress		12	Porcine Small Intestine submucosa,	
13	Urinary Incontinence		13	polypropylene mesh and autologous	
14	Exhibit 11 - AUGS Position Statement on	146	14	fascia in the rabbit model:	
15	Restriction of Surgical Options		15	implications for sling surgery	
16	for Pelvic Floor Disorders		16	Exhibit 25 - Urology, Time-Dependent Variations	293
17	Exhibit 12 - EAU Guidelines on Surgical	151	17	in inflammation and scar formation	
18	Treatment of Urinary Incontinence		18	of six different pubovaginal sling	
19	Exhibit 13 - EAU Guidelines on Urinary	154	19	materials in the rabbit model	
20	Incontinence		20		
21	Exhibit 14 - ICS Fact Sheets	155	21		
22	Exhibit 15 - NICE Urinary Incontinence: The	160	22		
23	management of urinary incontinence		23		
24	in women		24		
25	Exhibit 16 - Mayo Clinic web site information	171	25		

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1	EXHIBITS (Continued)		1	(Exhibit 1 marked.)	
2	NUMBER	PAGE	2	DANIEL STEVEN ELLIOTT, M.D.,	
3	Exhibit 17 - International Urogynecology Journal	178	3	a witness, being first duly sworn, testified as	
4	Long-term Results of the Tension-Free		4	follows:	
5	Vaginal Tape (TVT) Procedure for		5	EXAMINATION	
6	Surgical Treatment of Female Stress		6	BY MR. SNELL:	
7	Urinary Incontinence		7	Q. Good morning, Dr. Elliott?	
8	Exhibit 18 - Neurourology and Urodynamics	185	8	A. Good morning.	
9	Minimally Invasive Synthetic		9	Q. Can you state your full name for the	
10	Suburethral Sling Operations for		10	record, please.	
11	Stress Urinary Incontinence in Women		11	A. Daniel Steven Elliott, S-t-e-v-e-n.	
12	A Short Version Cochrane Review		12	Q. You and I know each other. I'll just	
13	Exhibit 19 - American Journal of Obstetrics and	204	13	forewarn you. I'm developing a cold and my voice	
14	Gynecology, A histologic and		14	is a little deep and cracky. And I have some	
15	immunohistochemical analysis of		15	water and I'll try to drink so it my speech is not	
16	defective vaginal healing after		16	impeded, but if you don't understand something I	
17	continence taping procedures:		17	say today, please tell me and I'll try to pose a	
18	A prospective case-controlled pilot		18	question that makes coherent sense to you.	
19	study		19	Is that okay?	
20	Exhibit 20 - Hernia Repair Sequelae	213	20	A. That is perfectly fine. Thank you.	
21	Exhibit 21 - International Urogynecologic	242	21	Q. All right. I've given you Exhibit 1,	
22	Journal, polypropylene as a		22	which is the notice for your deposition.	
23	reinforcement in pelvic surgery		23	Have you seen that document before?	
24	is not inert: Comparative		24	A. Yes.	
25	analysis of 100 explants		25	Q. All right. And what, if anything, did	

3 (Pages 6 to 9)

Daniel Steven Elliott, M.D.

Page 10	Page 12
<p>1 you do to comply with the request that you bring</p> <p>2 documents and materials that is attached to that</p> <p>3 request?</p> <p>4 A. I provided up-to-date -- well, you</p> <p>5 have already a copy of my CV. I have -- which I</p> <p>6 can provide to you. There are five new things.</p> <p>7 Just as far as what has been published, which I</p> <p>8 can provide to you there. That's a -- and then</p> <p>9 that is a copy of the manuscript, that number 5,</p> <p>10 because that just came out yesterday. So I didn't</p> <p>11 have that typed up.</p> <p>12 Q. Did you bring your file here today?</p> <p>13 A. The file? I'm sorry.</p> <p>14 Q. I guess, did you bring your expert</p> <p>15 file here today that would contain the documents</p> <p>16 and materials that you reviewed and are relying</p> <p>17 on?</p> <p>18 MR. CARTMELL: We can just -- for the</p> <p>19 record, we can get a thumb drive of everything</p> <p>20 that's on his reliance list, including that</p> <p>21 update. I just need to talk to Kuntz about that.</p> <p>22 I don't have the thumb drive with me today.</p> <p>23 Q. BY MR. SNELL: Do you have the thumb</p> <p>24 drive, Doctor?</p> <p>25 A. No. I don't have that, no. I have my</p>	<p>1 education committee. Minnesota Medical Society.</p> <p>2 Zumbro Valley Medical Society. Olmsted Community</p> <p>3 Medical Society. International Urogynecologic</p> <p>4 Society. Society of Urologic Prosthetic Surgeons.</p> <p>5 Society of Laparoendoscopic Surgeons. Minimally</p> <p>6 Invasive Robotic Association. Minnesota Urologic</p> <p>7 Society. European Association of Urology, which I</p> <p>8 am a member of, an international member, and then</p> <p>9 I'm also a member of the subsection of</p> <p>10 Genitourinary Reconstructive Surgeons, and also a</p> <p>11 member of the section of the Female Urology and</p> <p>12 Functional Urology. And again that's underneath</p> <p>13 the umbrella of the European Urology Association.</p> <p>14 International Urogynecologic Association.</p> <p>15 International Pelvic Pain Society.</p> <p>16 Q. In your role on the education</p> <p>17 committee for SUFU -- and that's the society of</p> <p>18 what?</p> <p>19 A. Good question. They changed the name.</p> <p>20 Society of Urodynamics and Female</p> <p>21 Urology is an acceptable -- but, again, they've</p> <p>22 actually moved around the words a bit there, but</p> <p>23 that's what it means.</p> <p>24 Q. Can I just call it SUFU?</p> <p>25 A. SUFU.</p>
Page 11	Page 13
<p>1 report. I do not have a copy of my reliance list.</p> <p>2 Q. Okay. So we'll mark as Exhibit 2 the</p> <p>3 five new studies that would go on your CV; is that</p> <p>4 correct?</p> <p>5 A. Correct. Those are my published</p> <p>6 studies, yes.</p> <p>7 (Exhibit 2 marked.)</p> <p>8 Q. BY MR. SNELL: We'll mark as Exhibit 3</p> <p>9 article number 5, which the lead author is Linder,</p> <p>10 L-i-n-d-e-r, then Chow, then Elliott. Long-term</p> <p>11 quality of life outcomes and retreatment rates</p> <p>12 after robotic sacrocolpopexy.</p> <p>13 (Exhibit 3 marked.)</p> <p>14 Q. BY MR. SNELL: To what professional</p> <p>15 societies do you currently belong to?</p> <p>16 A. That would be in my CV. Let me see if</p> <p>17 I have a copy of my CV. I might not. Oh, I do</p> <p>18 have one.</p> <p>19 Professional societies are going to be</p> <p>20 listed in the professional membership society on</p> <p>21 page 3 of 25. AMA, American Medical Association.</p> <p>22 American Association of Clinical Urologists.</p> <p>23 American Urologic Association. International</p> <p>24 Incontinent Society. Society of Urodynamics and</p> <p>25 Female Urology, which I am a member and on the</p>	<p>1 Q. Make it easier on the court reporter,</p> <p>2 too.</p> <p>3 A. SUFU is much better. I prefer that.</p> <p>4 Q. SUFU in all caps. Okay. What is your</p> <p>5 role -- strike that.</p> <p>6 What do you do in your role as being</p> <p>7 on the education committee for SUFU?</p> <p>8 A. It is a -- focusing on the education</p> <p>9 not only of the current residents of what we feel</p> <p>10 would be appropriate for training in female</p> <p>11 urology, urinary incontinence and prolapse, but</p> <p>12 also determining goals, objectives of education at</p> <p>13 meetings and lecture topics, things like that.</p> <p>14 Q. You've given testimony in the past;</p> <p>15 correct?</p> <p>16 A. Correct.</p> <p>17 Q. I've deposed you in the past; correct?</p> <p>18 A. Twice, I believe, yes.</p> <p>19 Q. So we can rely on your prior</p> <p>20 testimony. We don't have to ask you those</p> <p>21 questions again; correct?</p> <p>22 A. Well, with the understanding that</p> <p>23 sometimes things have changed, but, yeah, as far</p> <p>24 as data being out, those types of things.</p> <p>25 Q. Okay.</p>

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<p style="text-align: right;">Page 14</p> <p>1 A. That's a broad question, because those 2 are depositions over two or three days -- or two 3 days, excuse me. So I'd have to see each specific 4 question what you're talking about. 5 Q. Okay. As you sit here today, is there 6 any testimony that you gave in the Bellew or Gross 7 cases that was inaccurate or untruthful? 8 A. No. They would all been truthful and 9 accurate, but as the -- as data becomes available, 10 more research being done, as I read more internal 11 documents, certain positions may change. But 12 there's nothing dishonest or deceitful. 13 Q. In connection with the education 14 committee for SUFU, you testified that one of the 15 things that you were involved in was looking at 16 the training that residents would need in urology, 17 female urology? 18 A. Looking at the goals or where we want 19 residents to be, what criteria or surgeries, 20 volumes, types of surgeries, testing, 21 credentialing. 22 Q. Okay. 23 A. All those issues. 24 Q. And for the EAU, can I call that the 25 European Association of Urology?</p>	<p style="text-align: right;">Page 16</p> <p>1 Q. Not really. 2 So just remind me, what section of the 3 EAU is focused on assessing the surgical options 4 for stress urinary incontinence? 5 A. That would be a function of the female 6 and functional urology. 7 Q. Are you a member of that section? 8 A. Correct. And I'm on the board of 9 that, yes. 10 Q. How long have you been on the board of 11 that section that assesses the surgical treatment 12 of stress incontinence? 13 A. Since April of 2013. 14 Q. Okay. What are your fees for your 15 work as an expert in this matter? 16 A. \$700 an hour. 17 Q. And what is your fees for testimony? 18 A. Same. \$700 an hour for everything. 19 Q. Plus travel expenses and costs? 20 A. Correct. 21 Q. How many hours have you worked on the 22 Mullins case. 23 And when I say Mullins, this is the 24 MDL design defect case. 25 A. As far as specifically on patient</p>
<p style="text-align: right;">Page 15</p> <p>1 A. EAU's easy, yeah. 2 Q. Okay. And you said you were a member 3 of the genitourinary section? 4 A. Yeah. The genitourinary 5 reconstructive. So it's reconstructive surgeons, 6 because my training is in female pelvic medicine 7 and reconstructive surgery, which are separate and 8 overlapping training. 9 Q. That would include the surgical 10 treatment of stress urinary incontinence? 11 A. That would be the other committee. 12 That would be the female urology and functional 13 urology. Reconstructive would be complications, 14 radiation damage, those types of things. Anytime 15 you hear of reconstructive, think of fixing 16 mistakes or problems. 17 Q. Are you a member of the section that 18 assesses surgical treatment options for stress 19 urinary incontinence for the EAU? 20 A. Well, the members of the female 21 functional -- we're not necessarily -- unlike the 22 SUFU, which is an education section, this is more 23 like the research that's being done. It's not 24 setting goals or guidelines by any means. I don't 25 know if that answers your questions or not.</p>	<p style="text-align: right;">Page 17</p> <p>1 Mullins, I have not reviewed her records. As far 2 as TVT and design, I guess I don't know 3 specifically -- specifically on the TVT and 4 design, it's going to be somewhat difficult to 5 ascertain exact time, because obviously the study 6 of Prolift factors in. 7 But as far as I can determine, roughly 8 60 hours have been spent as of August 31st, 2015. 9 60 hours. 10 Q. How many hours have you spent since 11 September 1st on this matter? 12 A. It's going to be difficult, because 13 there's also travel involved in there. So I don't 14 know if you want the total hours, because that's 15 not also study on things. But that'd be about 16 110 hours. 17 Q. Do you bill \$700 an hour when you 18 travel? 19 A. Correct. 20 Q. Do you issue invoices for your time 21 spent on this matter? 22 A. Correct. 23 Q. Do you send those to Ben Anderson? 24 A. Correct. 25 Q. And would those invoices be specific</p>

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<p>1 to and reference your work in the Mullins' TVT 2 design defect case? 3 A. It will be specific to Ethicon. 4 Q. Okay. 5 A. So that's why it's difficult to 6 determine exact number of hours, and that data 7 reviewed two years ago is pertinent to now. So 8 that's why it's difficult to know the total 9 number. 10 Q. You're serving as an expert against 11 other mesh manufacturers? 12 A. Yes. Mentor ObTape. 13 Q. Any others? 14 A. There was start in the Cook Surgisis 15 mesh, but last I've heard there's no action going 16 on with that. 17 I have been deposed with Avaulta. 18 But, again, nothing has happened with that in six 19 months, and I don't know where the status of those 20 are. 21 Q. Avaulta, is that a Bard product? 22 A. Correct. 23 Q. That's a prolapse product? 24 A. Prolapse product; correct. 25 Q. Okay. Does the Mayo Clinic know that</p>	<p>1 A. The answer to that probably would be 2 no. I could be involved in the cases, but I am 3 not the one sitting behind the robot. I am the 4 one involved directing traffic as far as the 5 dissection goes. 6 Q. Okay. What surgical options do you 7 currently use for the treatment of stress urinary 8 incontinence in your patients, if any? 9 A. Autologous pubovaginal sling, 10 cadaveric pubovaginal sling, autologous obturator 11 vagina sling, and then in the past since August of 12 2013, there's been one mesh sling. So that is a 13 change from previous testimony. 14 Q. How many autologous transobturator 15 slings do you use on average each year? 16 A. Probably it's around 80 or so. That's 17 a rough -- that's a rough number. It varies from 18 time to time. But in the past two years or -- 19 yeah, two years now, I'd say 80 a year's probably 20 accurate. 21 Q. And that's the autologous 22 transobturator sling? 23 A. Correct. 24 Q. I know you published a feasibility 25 cohort study on very small sample size for the</p>
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<p>1 you're serving as an expert for plaintiffs in the 2 mesh litigation? 3 A. No. This is all done by private time. 4 Q. I know I deposed you in two prolapse 5 cases in the past. So today I'm really focused on 6 stress urinary incontinence; all right? 7 A. Correct. 8 Q. With that said, though, let me just 9 ask you this question. 10 In the Bellew deposition you testified 11 about treatment options you used for prolapse. 12 Do you recall that, in general? 13 A. Correct. 14 Q. Have those changed as we sit here 15 today? 16 A. No. 17 Q. For Exhibit 3, the robotic 18 sacrocolpopexy cohort that you published on -- 19 A. Yes. 20 Q. -- am I correct that you're not the 21 one who runs and operates the robot? 22 A. No. Dr. Chow does that. 23 Q. Okay. Are you credentialed at Mayo 24 Clinic to run the robot for sacrocolpopexy 25 procedures?</p>	<p>1 autologous transobturator pubovaginal sling; 2 correct? 3 A. Correct. 4 Q. That was ten patients; correct? 5 A. I believe so. It was ten patients, 6 yes. 7 Q. There's a 20 percent failure rate at a 8 mean average of four months' follow-up; correct? 9 A. Yeah. That data is now -- we're 10 looking at 60 patients with one year. 11 Q. Has that data been published? 12 A. That's in the process of being 13 gathered right now. All patients are being 14 contacted. 15 Q. How many patients are going to be in 16 that cohort, you said? 17 A. 60. It's a continuation of 18 feasibility study. Looking at safety, efficacy, 19 complications, et cetera. 20 Q. Has that data been presented anywhere 21 in abstract form or oral presentation? 22 A. Yes. I'd have to go back to the CV. 23 It was presented in February of 2015 at SUFU. 24 Again, that was the initial feasibility study. 25 Q. I think my question maybe wasn't</p>

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<p>1 clear.</p> <p>2 So on this updated cohort of 60</p> <p>3 patients --</p> <p>4 A. Oh, I see.</p> <p>5 Q. -- have you presented on those data</p> <p>6 anywhere?</p> <p>7 A. No. Not in the updated, no.</p> <p>8 Q. And then the small feasibility study</p> <p>9 that you did publish on, you recall the mean</p> <p>10 follow-up time was to four months?</p> <p>11 A. It was short-term, yes.</p> <p>12 Q. What's a feasibility study?</p> <p>13 A. Feasibility is a small cohort of</p> <p>14 patients that understand that they're involved in</p> <p>15 a study to determine whether or not this is a good</p> <p>16 treatment option, where we're doing quality of</p> <p>17 life assessments prior to and afterwards and</p> <p>18 following very closely, looking at complications</p> <p>19 and efficacy with 24-hour PAD tests.</p> <p>20 Q. How many cadaver slings do you use on</p> <p>21 average each year? And if that's changed year to</p> <p>22 year, you can tell me that.</p> <p>23 A. Yeah. The numbers are so -- quite</p> <p>24 variable. So it's difficult to give you a number</p> <p>25 I would say autologous slings are probably going</p>	<p>1 their tissue. Because mostly what I'm seeing in</p> <p>2 my practice is somebody that's been operated on</p> <p>3 multiple times. I'm not seeing usually the</p> <p>4 first-time patient. So, again, there's multiple</p> <p>5 patient variables.</p> <p>6 Q. Do you have patients for whom you</p> <p>7 offer the autologous pubovaginal sling and who</p> <p>8 decline that operation?</p> <p>9 A. I suppose that could occur, but</p> <p>10 usually those individuals are declining surgery</p> <p>11 period, not declining the autologous sling. So we</p> <p>12 have to be very careful how we're phrasing that.</p> <p>13 They are not a surgical candidate or they're</p> <p>14 choosing not to undergo surgery for their</p> <p>15 treatment. They're not saying, I do not want a</p> <p>16 autologous sling.</p> <p>17 Q. Are there patients for whom you've</p> <p>18 treated that do not want a cadaveric sling?</p> <p>19 A. I have not encountered that, no.</p> <p>20 Q. Is the autologous transobturator sling</p> <p>21 the primary -- sounds like it's the primary stress</p> <p>22 urinary incontinence surgery you're doing?</p> <p>23 A. Primary being the most common?</p> <p>24 Q. Yes, sir.</p> <p>25 A. That would be correct, sir, at this</p>
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<p>1 to be around, let's say, 30 or so. And then</p> <p>2 cadaverics are probably going to be probably less</p> <p>3 than that. Probably 10 or so a year.</p> <p>4 Q. You do about 30 or so autologous</p> <p>5 pubovaginal slings; correct?</p> <p>6 A. About 30 a year, yes. And that will</p> <p>7 vary dramatically, yes.</p> <p>8 Q. And that's the traditional pubovaginal</p> <p>9 sling procedure that's been referenced in the</p> <p>10 literature for decades?</p> <p>11 A. Yes. With the understanding that the</p> <p>12 term "pubovaginal" is not necessarily a specific</p> <p>13 way of doing it, but in general, you are correct.</p> <p>14 Q. And that's the sling that's -- where</p> <p>15 the tissue is harvested from the patient herself;</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. Okay. And the autologous pubovaginal</p> <p>19 sling is not a medical device; is it?</p> <p>20 A. Correct. It is not.</p> <p>21 Q. Why do you only use 10 or so cadaveric</p> <p>22 slings a year?</p> <p>23 A. It's going to be dependent upon the</p> <p>24 patients, the specific patient, the criteria they</p> <p>25 have, multiple different surgeries, the quality of</p>	<p>1 point. But, again, we're going to analyze the</p> <p>2 data.</p> <p>3 Q. And the autologous transobturator</p> <p>4 sling is not a medical device; is that correct?</p> <p>5 A. That's correct.</p> <p>6 Q. The cadaveric sling is not a medical</p> <p>7 device; correct?</p> <p>8 A. Well, it's -- it's a device -- it's a</p> <p>9 product that is purchased from the company</p> <p>10 Coloplast. So I don't think it qualifies. It's</p> <p>11 not a man-made device.</p> <p>12 Q. It's harvested from a dead person;</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 Q. And the one mesh sling you used, I</p> <p>16 think you said in August of 2013?</p> <p>17 A. Correct.</p> <p>18 Q. What type of mesh sling was that?</p> <p>19 A. That was a Coloplast product, the</p> <p>20 Supris.</p> <p>21 Q. Why did you only use that Coloplast</p> <p>22 Supris on one occasion?</p> <p>23 A. That was -- I can't recall the exact</p> <p>24 patient issues with that one. There was some</p> <p>25 reason why we did not -- and that's one -- it</p>

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<p>1 wasn't in August of 2013. It's since August of</p> <p>2 2013 there's only been one. So it's a major shift</p> <p>3 in my practice. And I don't recall the reasons</p> <p>4 why we chose it, but there was a medically</p> <p>5 necessary reason, in my opinion, to do it.</p> <p>6 Q. What type of material is the Coloplast</p> <p>7 material made of?</p> <p>8 A. It is a polypropylene mesh.</p> <p>9 Q. And what route is the Coloplast Supris</p> <p>10 sling placed?</p> <p>11 A. It's a suprapubic approach.</p> <p>12 Transvaginal suprapubic.</p> <p>13 Q. Can you explain that to me? I'm</p> <p>14 familiar with retropubic and transobturator.</p> <p>15 A. Well, retropubic, all that means is</p> <p>16 behind the pubic bone. So it doesn't describe to</p> <p>17 a surgeon -- it doesn't describe -- it just</p> <p>18 describes an anatomical location. The TVT is</p> <p>19 bottom up. Supris or Sparc is top-down. That's</p> <p>20 probably -- that's the easier way to --</p> <p>21 Q. So the Colopress -- strike that.</p> <p>22 The Coloplast Supris polypropylene</p> <p>23 mesh sling uses a top-to-bottom approach?</p> <p>24 A. Correct.</p> <p>25 Q. And just so I'm clear, you've used</p>	<p>1 Q. In the past 10 years, have you used</p> <p>2 the Birch colposuspension?</p> <p>3 A. No, I have not.</p> <p>4 Q. In the past 10 years, have you used</p> <p>5 the Marshall-Marchetti-Krantz colposuspension</p> <p>6 procedure?</p> <p>7 A. No, I have not. I have not</p> <p>8 personally. I've been involved in cases -- I</p> <p>9 should take that back or strike it whatever your</p> <p>10 legal terminology is.</p> <p>11 I have been involved with GYN cases</p> <p>12 who have done the Burch. I was not the surgeon</p> <p>13 doing the Burch. I was doing something else. But</p> <p>14 I have not personally done the Burch or the MMK</p> <p>15 since fellowship, which was in '99 to 2000.</p> <p>16 Q. How many Burch procedures have you</p> <p>17 personally done in your career?</p> <p>18 A. Probably two.</p> <p>19 Q. How many MMK procedures have you</p> <p>20 personally done in your career?</p> <p>21 A. Zero.</p> <p>22 Q. The Burch colposuspension is not a</p> <p>23 medical device; correct?</p> <p>24 A. Correct.</p> <p>25 Q. Besides the Supris Coloplast sling,</p>
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<p>1 that sling on one occasion only?</p> <p>2 A. No. No. I've used that once since</p> <p>3 August of 2013. Prior to that, I probably placed</p> <p>4 1200 or so. For a while there I was doing 100 to</p> <p>5 150 slings a year. Those were synthetic slings.</p> <p>6 Those were the Coloplast, and that started in 2004</p> <p>7 or so. So whatever the math is on that. So prior</p> <p>8 to that I used another product. So what I'm</p> <p>9 saying is I've stopped using polypropylene as a</p> <p>10 first line treatment.</p> <p>11 Q. So from 2004 up to around the midpoint</p> <p>12 of 2013, August 2013 --</p> <p>13 A. Correct.</p> <p>14 Q. -- you used Coloplast polypropylene</p> <p>15 mesh slings as your primary surgical option for</p> <p>16 the treatment of stress urinary incontinence?</p> <p>17 A. That's correct. At some point in</p> <p>18 time -- I cannot recall the exact dates -- I</p> <p>19 changed from using the AMS product, because of the</p> <p>20 problems I was having with it, to the Coloplast</p> <p>21 product. Again, we have to take with a grain of</p> <p>22 salt, it was 2004, 2005, in that time frame. And</p> <p>23 then it was exclusively the Coloplast product. No</p> <p>24 other product. No other polypropylene mesh was</p> <p>25 used.</p>	<p>1 what other Coloplast slings did you use?</p> <p>2 A. The Aris. A-i -- excuse me, A-r-i-s.</p> <p>3 That is the transobturator. Same mesh, just a</p> <p>4 different route.</p> <p>5 Q. So I take it you would have began</p> <p>6 using the Coloplast Supris before the Coloplast</p> <p>7 Aris sling?</p> <p>8 A. I don't recall the sequence of how</p> <p>9 they were introduced. So it would have been about</p> <p>10 the same time, because in that time frame,</p> <p>11 transobturator route was available and suprapubic</p> <p>12 route, or top-down was available. I would think I</p> <p>13 probably started using both at the same time, if</p> <p>14 they were available. I don't recall exactly.</p> <p>15 Q. Okay. You mentioned you had some</p> <p>16 problems with AMS slings.</p> <p>17 A. Correct.</p> <p>18 Q. Were those AMS polypropylene slings?</p> <p>19 A. Correct. The Sparc, S-p-a-r-c, and</p> <p>20 the Monarc, M-o-n-a-r-c. Because of those</p> <p>21 problems, I stopped using the product.</p> <p>22 Q. Sparc is a retropubic sling?</p> <p>23 A. Correct. Top-down.</p> <p>24 Q. Top-down. And Monarc, as I understand</p> <p>25 it, is an outside and transobturator sling?</p>

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<p>1 A. Correct.</p> <p>2 Q. How many AMS slings do you think you</p> <p>3 placed in your career made of polypropylene?</p> <p>4 A. Yeah. I initially started -- I'll</p> <p>5 answer your question. This is complicated. I</p> <p>6 initially started using the ObTape, which was a</p> <p>7 transobturator Mentor product. Had a horrible</p> <p>8 amount of complications.</p> <p>9 So around in 2004 -- excuse me,</p> <p>10 2003 -- again, I don't recall the exact dates -- I</p> <p>11 changed over to the AMS product. And so I</p> <p>12 probably placed in a period of a year or two until</p> <p>13 the Coloplast product became available -- so you</p> <p>14 have to understand this is a guesstimate -- 100 to</p> <p>15 150 a year. So we can say 2 to 300, maybe.</p> <p>16 Q. Okay. So am I correct that the ObTape</p> <p>17 was the first synthetic sling you placed for the</p> <p>18 surgical treatment of stress urinary incontinence?</p> <p>19 A. Okay. We're going back 13, 14,</p> <p>20 15 years now. That was a transobturator route.</p> <p>21 So I was doing suprapubic prior to that. I was</p> <p>22 the first in the state of Minnesota and possibly</p> <p>23 the first in the United States to use the ObTape.</p> <p>24 At least that's what the company told me. So I</p> <p>25 was actually using the Sparc prior to that. And,</p>	<p>1 with the AMS Sparc and Monarc problems? Strike</p> <p>2 that. That was a bad question. I need water.</p> <p>3 When do you recall first using the</p> <p>4 ObTape?</p> <p>5 A. I'd be able to search my records and</p> <p>6 give you a pretty close to accurate date, but it</p> <p>7 would have been about in 2003, about in October or</p> <p>8 so.</p> <p>9 Q. You did a fellowship; right?</p> <p>10 A. Correct.</p> <p>11 Q. What surgeries did you learn to do to</p> <p>12 treat stress urinary incontinence during your</p> <p>13 fellowship?</p> <p>14 A. Well, that's where we did a Burch. So</p> <p>15 I'd never done Burch in residency. We only did</p> <p>16 one or two.</p> <p>17 Q. Okay.</p> <p>18 A. Where I was the surgeon or under the</p> <p>19 leadership of a staff.</p> <p>20 I had already done autologous slings.</p> <p>21 So I improved my skills. I wouldn't say I was</p> <p>22 learning something new.</p> <p>23 And then the cadaveric sling I learned</p> <p>24 there.</p> <p>25 Q. Okay.</p>
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<p>1 again, I know it's going to be difficult. I'm not</p> <p>2 trying to be difficult. I just can't recall the</p> <p>3 exact -- so I was definitively using suprapubic</p> <p>4 prior to that time. And then transobturator came</p> <p>5 out. The Mentor at the time had the patent, two</p> <p>6 transobturators. They were the first ones to do</p> <p>7 it. So I would have used a suprapubic route</p> <p>8 first. Then transobturator with Mentor. Had</p> <p>9 problems. Then swapped over to the AMS Monarc</p> <p>10 would probably be the sequence of things.</p> <p>11 Q. What kind of problems did you have</p> <p>12 with the ObTape sling?</p> <p>13 A. You name it. It was a terrible</p> <p>14 device. It was problems of buttock abscess.</p> <p>15 Extrusion rate. Pushing out. Pain. I did it in</p> <p>16 110 patients, and we had 9 come back within a year</p> <p>17 or so with obturator fossa abscess, buttock</p> <p>18 abscess, extrusion. And then I had one patient</p> <p>19 come back in 2013. So what's that? Eight years</p> <p>20 after I implanted it with another extrusion.</p> <p>21 Q. So you had a total of 10 patients who</p> <p>22 came back with some type of complication out of</p> <p>23 110 for the ObTape?</p> <p>24 A. Correct. That I know of.</p> <p>25 Q. What type of problems did you have</p>	<p>1 A. Or first did there. I knew about it,</p> <p>2 but had first performed the procedure.</p> <p>3 Q. In your residency, what stress urinary</p> <p>4 incontinence surgeries did you learn about?</p> <p>5 A. Only pubovaginal, autologous</p> <p>6 pubovaginal sling.</p> <p>7 Q. Is it correct that in your fellowship</p> <p>8 you did not learn -- strike that.</p> <p>9 Is it correct in your fellowship you</p> <p>10 did not perform any synthetic slings to treat</p> <p>11 stress urinary incontinence?</p> <p>12 A. That is correct. At that point in</p> <p>13 time, only the TVT was available. My staff and</p> <p>14 residency and then my fellowship staff both did</p> <p>15 not feel it was safe; so did not do it. So my</p> <p>16 first synthetic came afterwards when the Sparc</p> <p>17 came out.</p> <p>18 Q. Is the retropubic mid-urethral sling</p> <p>19 taught in Mayo Clinic in residencies?</p> <p>20 A. It is not taught in the urology</p> <p>21 department. I cannot speak for the urogynecology</p> <p>22 department.</p> <p>23 Q. Is the retropubic mid-urethral</p> <p>24 polypropylene sling taught in fellowship at Mayo</p> <p>25 Clinic?</p>

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<p style="text-align: right;">Page 34</p> <p>1 A. Well, that would just be in the 2 urogynecology department. We do not have a 3 fellowship. So I don't know what they learn 4 there. 5 Q. So circling back around to the AMS 6 sling problems that you had, what were those with 7 the Sparc and the Monarc? 8 A. We'd have to divide it up into each 9 one, if you want. Kind of a -- because suprapubic 10 approach, the Sparc, had different complications 11 than the transobturator route. 12 Q. Okay. Let's go with Sparc first, and 13 thanks for that clarification. 14 A. Sparc -- 15 Q. Let me just get a good question. That 16 was a bad question on the record. 17 Can you tell me the problems you saw 18 with the AMS Sparc device? 19 A. Yeah. With the Sparc, it was the 20 top-down route. We had the problem with about a 21 10 percent bladder perforation rate. And then 22 also we had the problem the connector of the 23 trochar to the mesh was bulky. 24 So per our routine, after we would 25 place our trochar we would perform a cystoscopic</p>	<p style="text-align: right;">Page 36</p> <p>1 A. I'm going to have to clarify that 2 statement. Actually, that's incorrect, because on 3 my CV that I turned in, we have written up the 4 largest series of bladder outlet obstruction 5 requiring urethrolisis. So in that series would 6 be some of those Sparcs that were obstructed. So 7 I don't -- I can't give you an exact number. So 8 that has been published on, yes. 9 Q. Okay. What was the rate of bladder 10 outlet obstruction with the Sparc device in your 11 hands? 12 A. I don't recall me personally having 13 one. The other -- my colleague had a few, about a 14 1 to 5 percent rate of obstruction. 15 Q. Who is your colleague? 16 A. Dr. Deborah Lightner. 17 Q. And what was your rate of mesh 18 extrusion with the Sparc? 19 A. I can just, off the top of my head, 20 remember a few. I did not keep accurate records 21 of the exact number of those. 22 Q. What was the rate of pain with the 23 Sparc? 24 A. When we closely -- you know, when we 25 asked patients to see them back, there was</p>
<p style="text-align: right;">Page 35</p> <p>1 exam, and we were discovering, after we had 2 attached the mesh and pull it through, we're 3 tearing the bladder. So we developed these bad 4 tears in the bladder, when we would unequivocally 5 confirmed there was no bladder hole there to start 6 off with. So that was an unacceptable 7 complication right there. 8 And then we were having a problem as 9 far as mesh extrusion and pain. Now, that's the 10 Sparc complications. 11 Q. What rate of mesh extrusion did you 12 have with the Sparc device? 13 A. It was around -- that's going to be 14 very difficult to say, because it's looking back 15 so far now. 16 Q. Let me withdraw and ask you a question 17 that I think is easier to answer, a least it may 18 lead me to where I may want to go. 19 Did you or anyone else ever publish on 20 these problems with the AMS Sparc device? 21 A. We never published. We spoke about -- 22 I spoke about it. But I never had any 23 publications on it. 24 Q. When you say you spoke about it, what 25 do you mean by that?</p>	<p style="text-align: right;">Page 37</p> <p>1 probably about a 5 percent risk, roughly, of 2 suprapubic pain or vaginal discomfort with it. 3 Q. It would be routine to have the 4 patients come back following stress incontinence 5 surgery with a mid-urethral sling? 6 A. Yes or no. It depends if we're doing 7 a study looking at something specifically. So we 8 do not have a standard protocol to follow-up with 9 them. 10 Q. So when you put in a trans -- strike 11 that. 12 When you put in a Sparc sling in a 13 patient, am I correct you did not have a specific 14 follow-up plan for the patient? 15 A. We had a -- based upon efficacy only 16 at that point in time. I remember, this is back 17 in 2002 or 2003. We were -- and if the patients 18 were happy, they were continent, then we did not 19 have a scheduled follow-up for them. 20 Q. For the autologous pubovaginal sling 21 that you would perform around that time, did you 22 have scheduled follow-ups for your patients? 23 A. During that time frame I performed 24 very few, almost down to zero a year. There may 25 be an occasional one for a complicated</p>

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<p style="text-align: right;">Page 38</p> <p>1 reconstruction. So for a period of, what, seven, 2 eight years my numbers of autologous slings was 3 negligible. 4 Q. The Aris sling is the one made by 5 Coloplast, which is a transobturator approach; 6 correct? 7 A. Correct. 8 Q. When you began using the Coloplast 9 Supris sling, how many randomized control trials, 10 if any, were there on that device? 11 A. I don't recall. 12 Q. As you sit here today, do you know if 13 there are any randomized control trials on the 14 Coloplast Supris device? 15 A. I don't recall. 16 Q. Do you know or do you -- you say you 17 don't recall. Do you know? 18 A. I don't know. I have not searched the 19 literature if there is or isn't. 20 Q. When you began using the Coloplast 21 Aris transobturator sling, were there any 22 randomized control trials that existed at that 23 time? 24 A. Again, I don't recall back then, no. 25 Q. As you sit here the today, do you know</p>	<p style="text-align: right;">Page 40</p> <p>1 There was no data. I recall trusting the company 2 that there had been data, but there apparently was 3 not. 4 Same answer for the Sparc that I 5 believe that was already on the market when I 6 began using it. 7 Q. But my question was for the Monarc. 8 When you began using the AMS Monarc transobturator 9 device, did you begin using it when it was 10 introduced to the market or sometime later? 11 A. It most likely would have been 12 sometime later. Again, I don't recall the exact 13 dates. 14 Q. When you began using the AMS Sparc 15 device, did you sit down and do a literature 16 search to ascertain what literature, if any, 17 existed on that device before using it? 18 A. The product was brand-new to the 19 market. So there was no independent research on 20 it and definitely no long-term studies on it. 21 Q. When you began using either the 22 Coloplast sling products, the Supris or the Aris 23 devices, did you sit down and do a literature 24 search to assess what information and data were 25 available on those products, if any, before using</p>
<p style="text-align: right;">Page 39</p> <p>1 if there are any randomized control trials on the 2 Aris Coloplast sling? 3 A. I don't know. I don't recall if there 4 are or are not. 5 Q. When you began using the AMS Sparc 6 polypropylene sling, were there any randomized 7 control trials that existed on that device at the 8 time? 9 A. I would have to theorize there were 10 not because it was a brand-new product on the 11 market. 12 Q. When you began using the AMS Monarc 13 device, were there any randomized control trials 14 on that device? 15 A. Same answer as before. I don't recall 16 if there were or were not. 17 Q. Did you began doing the AMS Monarc 18 transobturator sling when it was introduced to the 19 market or did you wait some time? 20 A. No. As I recall, I used the Mentor 21 ObTape first for transobturator route. Again, as 22 I was told by the company, I was the first in the 23 state of Minnesota and possibly first in the 24 United States to do transobturator because it was 25 brand-new. So that answers a lot of questions.</p>	<p style="text-align: right;">Page 41</p> <p>1 those products? 2 A. I don't recall what I did at that 3 point in time, but there definitely were no 4 long-term studies because it was new to the 5 market. 6 Q. Now, when you began doing the AMS 7 Monarc procedure, did you do a literature search 8 to see if there was any data on that particular 9 device before using it in women? 10 A. Again, same answer as -- there was no 11 long-term studies. I don't recall if I did any 12 literature searches on it or not. I was provided 13 literature by the company, but, again, there was 14 no long-term studies. 15 Q. What literature were you provided by 16 the company on the AMS Monarc sling? 17 A. Their IFU and then their product 18 publicity statement, so to speak, that has the 19 blurbs on the product and how it's to be used and 20 things like that, with, you know, criteria, those 21 type things. 22 Q. Did AMS give you any published 23 clinical studies or abstracts of clinical studies 24 at the time they gave you the IFU or the publicity 25 statement for the Monarc device?</p>

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<p>1 A. I cannot recall exactly what happened.</p> <p>2 The -- it is part of the routine of most of these</p> <p>3 reps to provide you with papers. And I don't</p> <p>4 recall that specifically with this one, no.</p> <p>5 Q. What was your mesh exposure rate, if</p> <p>6 anything, with the Coloplast Supris device?</p> <p>7 A. That I am aware of, I've had two.</p> <p>8 Q. How many mesh exposures did you have</p> <p>9 with the Coloplast Aris device?</p> <p>10 A. Oh, I'm sorry. I misspoke. Of all</p> <p>11 the -- of all the Coloplast products combined, I</p> <p>12 know of two that I've had so far. I don't know</p> <p>13 which one was which, though.</p> <p>14 Q. Okay. So it would be fair to say for</p> <p>15 the Coloplast stress incontinence polypropylene</p> <p>16 mid-urethral slings you used, those being the</p> <p>17 Supris and the Aris, you're aware of two mesh</p> <p>18 exposures?</p> <p>19 A. Correct.</p> <p>20 Q. Okay. When was the last time you used</p> <p>21 a polypropylene mid-urethral sling to treat stress</p> <p>22 urinary incontinence that utilized a top-down</p> <p>23 approach?</p> <p>24 A. That would have been the one that I</p> <p>25 did between August of 2013 to the present, and it</p>	<p>1 recall ever seeing one of my patients who was</p> <p>2 obstructed afterwards.</p> <p>3 Q. Okay. What was your rate of obturator</p> <p>4 pain you saw with the Monarc device?</p> <p>5 A. Initially was essentially 100 percent.</p> <p>6 Markedly more than the ObTape. The ObTape when</p> <p>7 you placed it, the patient initially did not</p> <p>8 complain of any obturator foramen pain. The</p> <p>9 Monarc, they complained of it significantly</p> <p>10 immediately postop. We had to give a lot more</p> <p>11 analgesic, keep patients in the hospital, those</p> <p>12 types of things. So it was unacceptable problem</p> <p>13 with the device from my perspective.</p> <p>14 Q. What was the rate of obturator pain in</p> <p>15 your Monarc patients at six months or greater?</p> <p>16 A. I don't recall. And I don't know if</p> <p>17 we ever looked at that.</p> <p>18 Q. What was the rate of dyspareunia in</p> <p>19 your Monarc patients?</p> <p>20 A. Same answer as before. I don't</p> <p>21 recall. We never did a formal study on that. So</p> <p>22 I don't know.</p> <p>23 Q. Why did you have -- strike that.</p> <p>24 Did you find that the rate of the</p> <p>25 abscesses in your use of ObTape was unacceptable?</p>
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<p>1 would have been -- I can't recall exactly. It may</p> <p>2 have been in 2013 or early 2014.</p> <p>3 Q. Have you ever placed a mid-urethral</p> <p>4 sling utilizing a retropubic approach from the</p> <p>5 bottom to the top like is employed with the TVT</p> <p>6 retropubic device?</p> <p>7 A. Never. I've seen it. But I have not</p> <p>8 performed it myself.</p> <p>9 Q. Okay. As between the -- so just so</p> <p>10 I'm clear. You've done transobturator</p> <p>11 mid-urethral polypropylene slings, and you've used</p> <p>12 suprapubic top to bottom polypropylene slings to</p> <p>13 treat stress urinary incontinence in your career?</p> <p>14 A. Correct.</p> <p>15 Q. What problems did you have with the</p> <p>16 AMS Monarc device, the transobturator device?</p> <p>17 A. Similar problems as with the</p> <p>18 suprapubic, the Sparc, in that the adaptor was</p> <p>19 very large. So as you pulled it through the</p> <p>20 obturator foramen, you had to pull very hard, tug</p> <p>21 on it, stretching the mesh, and then it'd come</p> <p>22 through forcefully. So obturator pain, patient</p> <p>23 discomfort with it. We had dyspareunia. And then</p> <p>24 you had some vaginal extrusions. I do not</p> <p>25 recall -- not that it didn't happen, I do not</p>	<p>1 A. Absolutely unacceptable.</p> <p>2 Q. Why did you have an unacceptable rate</p> <p>3 of abscesses in the ObTape?</p> <p>4 A. That was with the design of the</p> <p>5 product. It was a heavy weight, essentially zero</p> <p>6 pore mesh, polypropylene mesh that transmitted</p> <p>7 infection through the obturator foramen to the</p> <p>8 buttock region.</p> <p>9 Q. For your Coloplast polypropylene</p> <p>10 slings, what type of efficacy did you see?</p> <p>11 A. Well, there's -- again, there's the</p> <p>12 suprapubic and the obturator route. We did</p> <p>13 never -- we never looked at our rate. So I can't</p> <p>14 tell you that. Though efficacy overall was</p> <p>15 acceptable.</p> <p>16 Q. With the AMS Sparc and Monarc devices,</p> <p>17 was your efficacy with those devices acceptable?</p> <p>18 A. Yes.</p> <p>19 Q. With the Coloplast polypropylene</p> <p>20 slings, did tissue integration occur with those</p> <p>21 devices?</p> <p>22 MR. SNELL: Object to form.</p> <p>23 A. The only way to know if there was</p> <p>24 tissue integration is to do a revision surgery on</p> <p>25 them. So we never did that.</p>

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<p style="text-align: right;">Page 46</p> <p>1 Q. BY MR. SNELL: Did any of your</p> <p>2 patients with the Coloplast slings made of</p> <p>3 polypropylene placed at the mid-urethral come back</p> <p>4 to you with their slings falling out?</p> <p>5 A. Well, yeah, we had two that I</p> <p>6 mentioned that I know of came out. So you could</p> <p>7 say those two had poor integration, but I cannot</p> <p>8 speak to the others, because we did not have a</p> <p>9 routine follow-up scheduled for them.</p> <p>10 Q. For the two patients I thought you</p> <p>11 told me they had mesh exposures.</p> <p>12 A. They did. So that's poor tissue</p> <p>13 integration.</p> <p>14 Q. What size were those exposures?</p> <p>15 A. I don't recall. They're probably</p> <p>16 around the range of a centimeter or so. It was</p> <p>17 not just a mild exposure. These required</p> <p>18 treatment.</p> <p>19 Q. And was the tissue integrated in the</p> <p>20 area beyond the mesh exposure in those two cases?</p> <p>21 A. Again, I can't recall going back that</p> <p>22 far. I know it was not at the location of the</p> <p>23 extrusion, though.</p> <p>24 Q. What was the pore size of the</p> <p>25 Coloplast polypropylene mesh?</p>	<p style="text-align: right;">Page 48</p> <p>1 Q. BY MR. SNELL: What was the weight of</p> <p>2 the Coloplast slings you used for stress urinary</p> <p>3 incontinence treatment?</p> <p>4 A. 70 grams per meter squared.</p> <p>5 Q. For the AMS Sparc and Monarc slings,</p> <p>6 what was the pore size of those products?</p> <p>7 A. Well, it depends if it's coming out of</p> <p>8 the box or once you've implanted it. And so the</p> <p>9 answer is, I don't know because it was quite</p> <p>10 variable. When you placed it in the patient and</p> <p>11 then pulled on the trochars, pulled the sheath</p> <p>12 around it, it would elongate and pull and roll up.</p> <p>13 And so you'd get this rope look appearance to it,</p> <p>14 which the pore size was zero, essentially --</p> <p>15 excuse me, not zero. It was negligible.</p> <p>16 Q. How many Sparc and Monarc slings did</p> <p>17 you place in your career?</p> <p>18 A. And that's in a period of probably</p> <p>19 two, maybe three years, a rate of 100 to 150 a</p> <p>20 year.</p> <p>21 Q. And when did you first see this roping</p> <p>22 and elongation of the Sparc and Monarc slings?</p> <p>23 A. As soon as we started putting it in.</p> <p>24 Q. So you began -- just so I understand,</p> <p>25 as soon as you began seeing -- strike that.</p>
<p style="text-align: right;">Page 47</p> <p>1 A. I don't know.</p> <p>2 Q. Was the Coloplast polypropylene</p> <p>3 mid-urethral sling mesh that you used mechanical</p> <p>4 cut or laser cut?</p> <p>5 A. It's actually different. It's hemmed.</p> <p>6 So the border of it looks completely different</p> <p>7 than the TVT or the Sparc. So you don't have the</p> <p>8 roping, the fraying particle loss with it or</p> <p>9 elongation. That's why I liked it over the Sparc</p> <p>10 procedure.</p> <p>11 Q. Did the Coloplast IFU for their sling</p> <p>12 products you used provide the frequency, severity,</p> <p>13 and duration of complications?</p> <p>14 A. I don't recall what the IFU said.</p> <p>15 Q. Did you read it?</p> <p>16 A. Yes, I read it.</p> <p>17 Q. As you sit here today, do you know</p> <p>18 whether those IFUs on the Coloplast mid-urethral</p> <p>19 slings ever reported frequency, severity, or</p> <p>20 duration of complications?</p> <p>21 MR. CARTMELL: Objection. Asked and</p> <p>22 answered. He just said he didn't recall.</p> <p>23 A. I don't recall, sir. It's been a long</p> <p>24 time. I know I'm required to review it, but I</p> <p>25 don't recall what they stated.</p>	<p style="text-align: right;">Page 49</p> <p>1 As soon as you began using the AMS</p> <p>2 polypropylene mid-urethral sling, you began seeing</p> <p>3 the roping and elongation?</p> <p>4 A. Correct.</p> <p>5 Q. Yet you continued to place 100 to 150</p> <p>6 of those a year?</p> <p>7 A. That is correct, because I didn't know</p> <p>8 the significance of it at the time.</p> <p>9 Q. Is the Sparc polypropylene sling</p> <p>10 mechanical cut or laser cut?</p> <p>11 A. I believe it is mechanical cut. In</p> <p>12 appearance it is identical to the TVT.</p> <p>13 Q. Does it have blue striping as well?</p> <p>14 A. Has a blue thread through it.</p> <p>15 Prolene -- or I believe it's Prolene suture. I'm</p> <p>16 not sure. And that was placed there not</p> <p>17 initially. That was placed afterwards to prevent</p> <p>18 the problem of it rolling, because when you'd</p> <p>19 tension it, it'd roll up.</p> <p>20 Q. And for the Monarc sling, is that</p> <p>21 mechanically cut or laser cut?</p> <p>22 A. Same answer as the Sparc. It appears</p> <p>23 to be mechanical cut. I can't speak for the cut.</p> <p>24 I've not reviewed those documents, but it appears</p> <p>25 to be mechanical cut.</p>

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<p style="text-align: right;">Page 50</p> <p>1 Q. Did you ever see particles falling off 2 of that mesh?</p> <p>3 A. When you would pull on it, either the 4 Monarc or the Sparc, they're the same mesh, you 5 would pull and then you would get these little 6 tiny fibers, like just little things that you 7 could actually see on your glove. And so the 8 answer to that question is yes.</p> <p>9 Q. And that did not deter you from using 10 those products?</p> <p>11 A. I was unaware of the significance at 12 the time.</p> <p>13 Q. Well, you knew you were implanting 14 polypropylene into the body; right?</p> <p>15 A. Correct.</p> <p>16 Q. And those little particles you would 17 see on your glove were made of what?</p> <p>18 A. Polypropylene.</p> <p>19 Q. Does the Monarc have the blue striping 20 as well?</p> <p>21 A. Yeah. It has a blue Prolene -- well, 22 I assume Prolene -- suture going through end to 23 end. That's for tensioning purposes. That was 24 added later.</p> <p>25 Q. Have you ever looked at the MSDS</p>	<p style="text-align: right;">Page 52</p> <p>1 A. I don't --</p> <p>2 MR. CARTMELL: Let me object to the 3 form.</p> <p>4 MR. SNELL: Okay.</p> <p>5 MR. CARTMELL: I'm not sure what 6 you're talking about, frankly, and I'm not sure he 7 will either. So it may call for speculation.</p> <p>8 A. I've reviewed a lot of documents, some 9 coming from Judge Goodwin. I don't recall the 10 nomenclature you're using.</p> <p>11 Q. BY MR. SNELL: Okay. Have you seen 12 any orders by Judge Goodwin in the Mullins case?</p> <p>13 A. Again, same answer as before. I 14 don't -- I've seen a lot of stuff coming from 15 Judge Goodwin with his signature or whatever on 16 it. I just don't recall the nomenclature you're 17 talking about.</p> <p>18 Q. I looked through your report, and your 19 footnotes begin on page 11; correct?</p> <p>20 A. That is correct.</p> <p>21 Q. Actually, if you turn to page 9, you 22 have a footnote at the top, but there's no 23 citation to it.</p> <p>24 A. Yeah. That is correct. That's a 25 typographical error, it looks, appears.</p>
<p style="text-align: right;">Page 51</p> <p>1 sheets that pertain to the Sparc or Monarc 2 products?</p> <p>3 A. No, I have not.</p> <p>4 Q. Have you ever looked at the MSDS 5 sheets that pertain to the Coloplast sling 6 products?</p> <p>7 A. I have not.</p> <p>8 Q. Why not?</p> <p>9 A. Because I don't know how to find them.</p> <p>10 Q. Am I correct; you never used the TVT 11 retropubic device?</p> <p>12 A. Correct. Correct. You're right.</p> <p>13 Q. And when I say TVT retropubic, I mean 14 the original, still-on-the-market-today Ethicon 15 manufactured TVT retropubic device.</p> <p>16 A. Correct. The bottom up. They also 17 have a top-down. But bottom line, I have not used 18 any Ethicon product for stress urinary 19 incontinence.</p> <p>20 Q. Okay. So that makes it fast. Great.</p> <p>21 Before writing your report in this 22 case, did you review the order issued by the judge 23 regarding the design defect claim in Mullins, and 24 what the judge expected the parties to focus on in 25 this matter?</p>	<p style="text-align: right;">Page 53</p> <p>1 Q. Okay.</p> <p>2 A. That's my comment. Yeah, there's no 3 reason to reference that.</p> <p>4 Q. Okay.</p> <p>5 A. That's my comment.</p> <p>6 Q. Okay. So looking at your report, 7 beginning on page 11 where you have Footnotes, the 8 majority of what you cite -- that way we can just 9 see if we can agree to this.</p> <p>10 In your expert report -- strike that.</p> <p>11 The majority of things that you cite 12 in your expert report in footnotes are either 13 Ethicon company documents, testimony by company 14 witnesses, or papers concerning hernia mesh or 15 prolapse.</p> <p>16 Is that a fair statement?</p> <p>17 MR. CARTMELL: Object to the form.</p> <p>18 A. Well, the majority -- you're correct.</p> <p>19 There's internal documentation. Many depositions. 20 There's the significant amount of medical 21 literature in the canine model, rabbit model, 22 human, and then there's TVT references in there, 23 too. So I can't say that -- there's a lot of 24 different references from a lot of different 25 sources.</p>

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<p style="text-align: right;">Page 54</p> <p>1 Q. BY MR. SNELL: Well, for the medical 2 literature, it's correct, isn't it, that you cited 3 to a lot more hernia literature than you did TVT 4 literature? 5 A. That is -- 6 MR. SNELL: Object to the form. 7 A. That is correct, because TVT is a 8 hernia mesh. 9 Q. BY MR. SNELL: And if we go to the 10 back of your report, on page 32, you cite to the 11 recent Cochrane Review by Ford, et al.? 12 A. Page 32? I'm sorry. 13 Q. Yes. Footnote 97, I see. 14 A. That is correct. 15 Q. What is a Cochrane Review? 16 A. Cochrane Review -- well, I actually 17 have a copy of it here. A Cochrane Review -- I 18 can give you the exact nomenclature that they use. 19 Yes. The Cochrane database, which is a -- I 20 believe it's government sponsored, that is in 21 charge of analyzing studies and a combination of 22 studies to hopefully be able to come up with 23 analysts -- analysis of papers and their efficacy, 24 their quality, et cetera. 25 (Exhibit 4 marked.)</p>	<p style="text-align: right;">Page 56</p> <p>1 large study. It's one of the bits of evidence. I 2 try to look at all evidence out there, whether it 3 be pro or con for mesh so I can get a balanced 4 opinion on this. And this is one of the 5 documents. And it's an updated one. 2015. 6 Q. Okay. Under the background, they 7 state that the mid-urethral sling operations are a 8 recognized minimally invasive surgical treatment 9 for stress urinary incontinence. 10 You see that? 11 A. That's what they state, yes. 12 Q. You would agree that the mid-urethral 13 sling is minimally invasive compared to the 14 autologous pubovaginal sling which requires 15 harvesting of tissue from the woman? 16 MR. CARTMELL: Object to the form. 17 A. I would agree, minimally invasive is 18 always a statement, has to be with qualifiers or a 19 comparison to. And I think it would be ligament 20 to say the mid-urethral sling is less invasive 21 than the autologous sling. 22 Q. BY MR. SNELL: Would you agree that 23 the mid-urethral sling, particularly the TVT 24 retropubic is less invasive than the Burch 25 colposuspension?</p>
<p style="text-align: right;">Page 55</p> <p>1 Q. BY MR. SNELL: I've handed you 2 Exhibit 4. This is the intervention review of 3 mid-urethral sling operations for stress urinary 4 incontinence in women by Dr. Ford and others; 5 correct? 6 A. Well, this is the abbreviated form of 7 it, the summary. 8 Q. Right. 9 A. The real document is -- I don't know 10 how many pages, but is a very big document. 11 Q. Right. 12 A. But, yes, this is the summary, as you 13 have stated. 14 Q. And this is the same Cochrane Review 15 you cited; correct? 16 A. Correct. One by Ford, et al., in 17 2015. 18 Q. And it looks like -- the publication 19 status and date, this actually -- Cochrane Review 20 was published this summer; correct? 21 A. July. Correct. 22 Q. And if you look in the abstract -- let 23 me ask you this: Why did you cite to the Cochrane 24 Review? 25 A. Multiple different reasons. It's a</p>	<p style="text-align: right;">Page 57</p> <p>1 MR. CARTMELL: Same objection. 2 A. You know, possibly. But, again, 3 depends how you do it. Some people can do it with 4 a very small incision, and it's -- but it depends 5 upon -- again, it's very difficult because you 6 have to pass those trochars blind. So that's an 7 invasive thing. It's a stab wound to a patient. 8 What's the difference in making an incision and 9 putting your stitches in. But you could say, yes, 10 it is going to be less -- the TVT is going to be 11 less invasive somewhat than the Burch. 12 Q. BY MR. SNELL: Would you agree that 13 the TVT retropubic device is less invasive than 14 doing an MMK? 15 A. I think, again, same as the Burch 16 answer. The MMK requires more lateral dissection. 17 So I think that's a fair statement. 18 Q. The MMK, as I understand it, has about 19 a 2.4 percent risk of the osteopubitis. Am I 20 saying that correctly? 21 A. Correct. It should not be that high 22 of a percentage, but that is a risk of it, 23 correct. 24 Q. But you've read literature summarizing 25 that risk is 2.4 percent by authors Drews and</p>

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<p>1 others?</p> <p>2 A. I've read literature from other people</p> <p>3 saying it is less than 1 percent. But I'm not</p> <p>4 going to deny it. Yes, there is a risk of that,</p> <p>5 and that's probably one of the reasons it's not</p> <p>6 done very much.</p> <p>7 Q. And how did patients in the MMK --</p> <p>8 strike that.</p> <p>9 The MMK is a open procedure?</p> <p>10 A. Correct. I don't recall anybody doing</p> <p>11 it laparoscopically, but it's a procedure not done</p> <p>12 very often anymore.</p> <p>13 Q. How does osteopubis occur in open</p> <p>14 procedure like the MMK?</p> <p>15 A. They're thinking it's irritation to</p> <p>16 the bone with the sutures.</p> <p>17 Q. The main results of this Cochrane</p> <p>18 Review -- I want to go down a little bit.</p> <p>19 First of all, they included 81 trials;</p> <p>20 correct? I'm on this page here, Doc.</p> <p>21 A. Oh, I'm sorry. Yes.</p> <p>22 Q. That evaluated 12,113 women; correct?</p> <p>23 A. Correct.</p> <p>24 Q. The quality of most outcomes was</p> <p>25 moderate; correct?</p>	<p>1 Q. And what is the importance, if any, of</p> <p>2 Oxford Levels of Evidence?</p> <p>3 A. It is trying to quantify or</p> <p>4 demonstrate or show individuals the data that is</p> <p>5 gathered from various different studies. It does</p> <p>6 not mean that other studies are invaluable, such</p> <p>7 as case reports. But when you're trying to</p> <p>8 compare apples to oranges or different types of</p> <p>9 apples to each other, you need to compare them</p> <p>10 directly to each other. And you get arguably the</p> <p>11 better data from that type of a study.</p> <p>12 Q. Level 1 you said was an RCT?</p> <p>13 A. Correct.</p> <p>14 Q. What is level 2?</p> <p>15 A. Level 2 is a case controlled trial.</p> <p>16 Comparisons are made, but they're not randomized.</p> <p>17 Q. You pulled out a document. Could we</p> <p>18 mark that as Exhibit 5? Thank you. Oh, okay.</p> <p>19 (Exhibit 5 marked.)</p> <p>20 Q. BY MR. SNELL: I just want to look at</p> <p>21 it real quick, and then I'll give it right back to</p> <p>22 you.</p> <p>23 So where would the Cochrane Review</p> <p>24 that you cited in your expert report rate on that</p> <p>25 level of evidence pyramid?</p>
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<p>1 A. Yes. It reads, "moderate, mainly due</p> <p>2 to bias or risk of imprecision."</p> <p>3 Q. And the vast majority of these studies</p> <p>4 that were included in the Ford Cochrane Review</p> <p>5 that you cited are what are called randomized</p> <p>6 control trials; correct?</p> <p>7 A. I'm sorry. I don't understand your</p> <p>8 question. Can you -- there's misspellings on</p> <p>9 that. So can you -- I'm sorry.</p> <p>10 Q. Do you know what a randomized control</p> <p>11 trial is?</p> <p>12 A. Yes, I do.</p> <p>13 Q. Of course you do. What is a</p> <p>14 randomized control trial?</p> <p>15 A. Randomized control trial would be a</p> <p>16 level 1 trial on the Oxford education levels,</p> <p>17 where there are two different groups that are</p> <p>18 equally randomized to two separate treatment arms.</p> <p>19 And then you do the same evaluations and the same</p> <p>20 pre and postop description of patients and</p> <p>21 outcomes.</p> <p>22 Q. Okay. You mentioned the Oxford. I've</p> <p>23 heard of the Oxford Levels of Evidence.</p> <p>24 Is that what you're referring to?</p> <p>25 A. Yes. That's fine.</p>	<p>1 A. Cochrane Review is really not on it.</p> <p>2 Cochrane Review is an analysis of all the data out</p> <p>3 there. It's like a meta-analysis. Meta-analysis</p> <p>4 which are used extensively don't fall into these</p> <p>5 categories. These are smaller studies. Cochrane</p> <p>6 or meta-analysis are a combination. Like they</p> <p>7 mentioned, 81 trials that evaluated 1200 patients.</p> <p>8 Hence the reason why there'll be weaknesses or</p> <p>9 errors within those studies because they're</p> <p>10 analyzing potentially bad studies.</p> <p>11 Q. I've seen a similar evidence pyramid</p> <p>12 that has on top, above an individual randomized</p> <p>13 control trial, something called systematic reviews</p> <p>14 in meta-analyses.</p> <p>15 A. Yeah. That's why I mentioned</p> <p>16 meta-analysis. I'm not familiar with that.</p> <p>17 Q. Okay.</p> <p>18 A. But, again, as I mentioned,</p> <p>19 meta-analysis, if you take bunches of poor quality</p> <p>20 studies, you're not going to get out of that</p> <p>21 magically a good quality study. If you take dog</p> <p>22 doo and make a lot of dog doo, you still have dog</p> <p>23 doo. So you have to be careful on those types of</p> <p>24 analyses. And that's why they mention here in</p> <p>25 this Cochrane one, the quality, at most, was</p>

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<p>1 moderate, and they indicate the reason why.</p> <p>2 Q. Do you rely on meta-analyses?</p> <p>3 A. I look -- I'm a reviewer for</p> <p>4 15 different journals, and twice been awarded the</p> <p>5 best reviewer in Journal of Urology. I look at</p> <p>6 them with skepticism, because it's just -- again,</p> <p>7 as I mentioned, you have to know what goes on on</p> <p>8 each and every study to know if it's a good</p> <p>9 quality study. If you take a lot of good quality</p> <p>10 studies and put them together, that's quality.</p> <p>11 And that's why there's going to be selection, and</p> <p>12 that's why certain studies won't meet criteria.</p> <p>13 But if you just take everything and analyze it,</p> <p>14 again, it's the -- a lot of dog doo. You got a</p> <p>15 big dog doo at the end.</p> <p>16 Q. So you are aware there's a Cochrane</p> <p>17 Review for the pubovaginal sling published by</p> <p>18 Remmen.</p> <p>19 A. I don't recall that title. I'd like</p> <p>20 to see that one. I don't recall that one.</p> <p>21 Q. Let me ask you this: Do you know if</p> <p>22 there's a Cochrane Review that analyzes the</p> <p>23 pubovaginal sling?</p> <p>24 A. Yes. By Remmen.</p> <p>25 Q. So if I mispronounce a name, you can</p>	<p>1 A. There's a paper by Chaken, et al.</p> <p>2 There's another one by McGuire's group at</p> <p>3 University of Michigan, both of which had</p> <p>4 100 percent patient involvement. Some up to --</p> <p>5 involvement. Contact. So zero dropout rate</p> <p>6 except for a death, and up to 10 years of</p> <p>7 follow-up.</p> <p>8 Q. Neither one of those studies are</p> <p>9 randomized control trials; correct?</p> <p>10 A. Correct.</p> <p>11 Q. They were both retrospective cohort</p> <p>12 studies; correct?</p> <p>13 A. Yeah. The data was prospectively</p> <p>14 gathered, retrospectively reviewed.</p> <p>15 Q. And they were single center studies;</p> <p>16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. And Ed McGuire is the surgeon you're</p> <p>19 referring to out of Michigan; correct?</p> <p>20 A. Well, he was actually down in Houston</p> <p>21 at the time that he wrote it, but he had been in</p> <p>22 Michigan.</p> <p>23 Q. For the Burch colposuspension, are</p> <p>24 there any high quality studies that you're aware</p> <p>25 of?</p>
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<p>1 answer yes and correct me. I'm okay with that.</p> <p>2 And the quality of evidence on the</p> <p>3 pubovaginal slings by Remmen was noted to be poor;</p> <p>4 correct?</p> <p>5 A. I don't recall. I'd have to see that.</p> <p>6 I have no reason to think -- I have no reason to</p> <p>7 think that you would be wrong with that, though.</p> <p>8 I'm going to see if I have that the study. Yeah.</p> <p>9 I don't -- without knowing how to spell it, I</p> <p>10 don't know how to find it. Okay.</p> <p>11 Q. You would agree that overall the</p> <p>12 quality of studies on pubovaginal slings is poor?</p> <p>13 A. I would say the overall studies on</p> <p>14 incontinence, in general, are moderate to poor.</p> <p>15 There are very few high quality studies out there.</p> <p>16 Q. But my question is specific to the</p> <p>17 autologous pubovaginal sling. You would agree for</p> <p>18 the autologous pubovaginal sling, the quality of</p> <p>19 evidence on that procedure is poor?</p> <p>20 A. As with all the other treatments, I</p> <p>21 would agree with you, yes.</p> <p>22 Q. You mentioned there were a few high</p> <p>23 quality studies. What would those be?</p> <p>24 A. For which procedure?</p> <p>25 Q. For the autologous pubovaginal sling.</p>	<p>1 A. Yeah, there are several. I have a</p> <p>2 Langer, et al., 10 to 15 years of follow-up, Burch</p> <p>3 colposuspension, from internal -- International</p> <p>4 Urogyn Journal.</p> <p>5 Q. Do you recall what the loss to</p> <p>6 follow-up was in the Langer Burch paper?</p> <p>7 A. Of the 156 patients, 29 were admitted</p> <p>8 for not completing a 10-year follow-up. 8</p> <p>9 patients died. Can't blame them for that. 21</p> <p>10 could not be located. So actually -- so they</p> <p>11 had -- death would not factor into it. So you</p> <p>12 have 21 out of 1156 were lost to follow-up.</p> <p>13 Q. The 29 patients, what happened with</p> <p>14 them?</p> <p>15 A. Well, that's what I'm saying. 29</p> <p>16 patients were not studied. 8 died.</p> <p>17 Q. Okay.</p> <p>18 A. And 21 could not be located. So that</p> <p>19 equals a percentage of 13 percent lost to</p> <p>20 follow-up.</p> <p>21 Q. And one of the issues or problems with</p> <p>22 longer term studies is that patients can die,</p> <p>23 succumb to mortality, as you follow over a decade</p> <p>24 or more; right?</p> <p>25 A. Correct.</p>

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<p>1 Q. And that's recognized in the field as</p> <p>2 an issue when looking at randomized -- strike</p> <p>3 that.</p> <p>4 When looking at longer term studies?</p> <p>5 A. Yes and no with that. Death is looked</p> <p>6 at differently than loss -- than a true loss to</p> <p>7 follow-up. They had the 21 patients that were not</p> <p>8 able to be located. Those are important. The 8</p> <p>9 that died are still important. It's sad they</p> <p>10 died, but you look at that data differently. And</p> <p>11 statistically it's different. And that's a</p> <p>12 follow-up over 12.4 years, median follow-up.</p> <p>13 And you also asked the question about</p> <p>14 other studies. There's also Herbertsson, et al.,</p> <p>15 H-e-r-b-e-r-t-s-o-n, and then I'll spell the next</p> <p>16 one, K-j-o-e-h-e-d-e, which had 14-year follow-up,</p> <p>17 and those are specifically on Burch. So here's</p> <p>18 three studies with greater than 10 years of</p> <p>19 follow-up.</p> <p>20 Q. Can I see the paper you were looking</p> <p>21 at real quick. Can we mark this, Doctor, as an</p> <p>22 exhibit?</p> <p>23 A. Sure.</p> <p>24 MR. SNELL: What number.</p> <p>25 (Exhibit 6 marked.)</p>	<p>1 to search for that.</p> <p>2 Q. Isn't 3.9 percent rate of dyspareunia</p> <p>3 with the Burch acceptable?</p> <p>4 A. Well, I think ideally you want a zero</p> <p>5 percent dyspareunia, but you'd have to know and</p> <p>6 which this study does not have, which I would</p> <p>7 critique if I were reviewing it, is a qualifier of</p> <p>8 how bad that dyspareunia is. Is it dryness or is</p> <p>9 it a complete inability to have intercourse due to</p> <p>10 pain, but it says 3.9 percent.</p> <p>11 Q. Right. And my question is: Is that</p> <p>12 3.9 percent rate of dyspareunia with the Burch in</p> <p>13 the paper review reference acceptable?</p> <p>14 MR. CARTMELL: Object to the form.</p> <p>15 A. Again, I need to know if it was</p> <p>16 de novo or not.</p> <p>17 Q. BY MR. SNELL: So you can't answer my</p> <p>18 question?</p> <p>19 A. I would, if I can find dyspareunia in</p> <p>20 here, where they discuss it. Yeah. I don't see</p> <p>21 it. We can take a long time. I can search for</p> <p>22 it. But I would need to see how they're</p> <p>23 describing it in those things.</p> <p>24 Q. I didn't see it either.</p> <p>25 A. That is an issue with many studies.</p>
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<p>1 Q. BY MR. SNELL: Look at table 5,</p> <p>2 Doctor.</p> <p>3 A. I'm there.</p> <p>4 Q. There's a 22 percent rate of detrusor</p> <p>5 instability; correct?</p> <p>6 A. That is what they quote, yes.</p> <p>7 Q. And what is that?</p> <p>8 A. That -- I'd have to see how they</p> <p>9 define it. De novo detrusor instability was found</p> <p>10 in 17 patients. So that means, following the</p> <p>11 procedure, it caused de novo overactive bladder</p> <p>12 symptoms. So their overall rate they state is 29.</p> <p>13 But only 17 of those were caused by the procedure.</p> <p>14 Q. Okay. So about two-thirds were caused</p> <p>15 by the procedure?</p> <p>16 A. Yeah. 58 percent. So 17 out of 127</p> <p>17 had de novo. 13 percent. So when you look at</p> <p>18 graphs and tables, that's why it's difficult to be</p> <p>19 a good reviewer. You have to look at the whole</p> <p>20 big picture. Not just one graph.</p> <p>21 Q. All right. The rate of dyspareunia</p> <p>22 was 3.9 percent in this Burch study?</p> <p>23 A. That is what they quote. Again, I'd</p> <p>24 have to look at the study exactly, if that's</p> <p>25 de novo or if that's preexisting or not. I'd have</p>	<p>1 It is not included. That's why we keep saying</p> <p>2 moderate quality. No. There's only -- in the</p> <p>3 document there's only one time they mention</p> <p>4 dyspareunia, and it's in that graph. So there's</p> <p>5 no qualifiers to it.</p> <p>6 Q. But it's still a paper you pointed me</p> <p>7 to as important with regard to the Burch</p> <p>8 colposuspension; correct?</p> <p>9 A. That is correct.</p> <p>10 Q. Back to the Cochrane Review. We were</p> <p>11 looking at the Results section in the fourth</p> <p>12 paragraph. It says, "The overall rate of vaginal</p> <p>13 tape erosion/extrusion/exposure was low in both</p> <p>14 groups." It was 21 out of 1,000 for retropubic</p> <p>15 mid-urethral sling.</p> <p>16 Do you see that?</p> <p>17 A. That is what they state for the study,</p> <p>18 yes.</p> <p>19 Q. That's 2.1 percent; correct?</p> <p>20 A. That is -- that is what they state,</p> <p>21 yes.</p> <p>22 Q. The 2.1 percent would be the incidents</p> <p>23 of the mesh exposure; correct?</p> <p>24 A. Well, that's what they state with the</p> <p>25 understanding that these are short-term, moderate</p>

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<p>1 quality studies, within the hands of high-quality 2 large volume surgeons. 3 Q. So these 31 trials that they assess, 4 did all of those trials involve short-term 5 follow-up? 6 A. Well, in the situation of meshes, this 7 is an implantable permanent medical device. 8 Anything short-term -- or short of lifelong 9 follow-up is going to be inadequate, from my 10 perspective. So this is going to be short-term. 11 I doubt any of these are over 10 years, and even 12 that, in my opinion, is inadequate. But you'd 13 have to look at each individual study to find out 14 what follow-up duration was. 15 MR. SNELL: Move to strike as 16 nonresponsive. 17 Q. BY MR. SNELL: The 31 trials that were 18 assessed, is it your testimony that all of those 19 trials are short-term trials? 20 MR. CARTMELL: Object to the form. 21 A. I would have to see this complete 22 document to see each of those follow-ups to see if 23 they're adequate or not. 24 Q. BY MR. SNELL: Is there any lifelong 25 follow-up data on the Burch colposuspension,</p>	<p>1 Q. BY MR. SNELL: Let me reask the 2 question. 3 For the Burch colposuspension, are 4 there any studies that have lifelong follow-up of 5 the patients? 6 A. As I stated, the Burch is not a 7 medical device. So, no, there are no long-term 8 studies, but there don't need to be because 9 there's no permanent implantable product in the 10 patient. 11 Q. But the Burch can lead to dyspareunia, 12 just like the paper you showed me; right? 13 A. No. I disagree with that. As I 14 stated, dyspareunia was recorded, but I have no 15 idea the preoperative incidence of dyspareunia. 16 Q. So it's not important to track 17 dyspareunia with the Burch colposuspension? 18 A. No. You are spinning my words. 19 That's incorrect. I stated, in that paper there's 20 one word of dyspareunia. I don't know; did 21 10 percent have dyspareunia preop? They don't 22 mention it. Hence the quality of the paper goes 23 down. 24 So from your argument, the 10 percent 25 could have been preop, now it's down 3.9. So they</p>
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<p>1 reporting a mean follow-up of 30, 40, 50, 60 years 2 in women? 3 A. Well, as you've pointed out, it's not 4 a medical device. There doesn't need to be. 5 There can be for efficacy, but for safety and 6 complications, that's going to be all 7 perioperative. So there does not need to be. 8 You're comparing apples to oranges. 9 MR. SNELL: Move to strike as 10 nonresponsive. 11 Q. BY MR. SNELL: For the Burch 12 colposuspension, are there any lifelong follow-up 13 studies? 14 MR. CARTMELL: Objection. Asked and 15 answered. He just answered your question. 16 MR. SNELL: I don't care whether he 17 thinks it's necessary or not. I'm asking him is 18 it -- all right. Do those exist. That's a yes or 19 no or he doesn't know. 20 MR. CARTMELL: Well, he said no and 21 explained why it's not important. 22 MR. SNELL: I don't think he said no, 23 Tom. He gave me a speech. 24 MR. CARTMELL: Well, you can say no, 25 and explain again why it's not important.</p>	<p>1 did a good job. 2 Q. Do you know which way it went? 3 A. As I stated, the paper does not 4 mention that. 5 Q. Is it important to track dyspareunia 6 with the Burch colposuspension? 7 MR. CARTMELL: Object to the form. 8 A. Dyspareunia and safety of the device 9 is always important to track. It's going to be 10 different for different products. If you have a 11 permanent implantable device, you have to follow 12 it lifelong. If you have a device that's 13 absorbed, gone away, it's not as important to 14 follow. 15 Q. BY MR. SNELL: So it's not as 16 important to follow dyspareunia with the Burch 17 colposuspension; is that what you're saying? 18 A. For as long a duration. 19 Q. Is it important to follow and assess 20 dyspareunia with the Burch colposuspension out to 21 10 years? 22 A. It would be an interesting fact. 23 However, again, there's no permanent devices 24 placed in a woman. So I am more concerned about 25 the shorter term, five years, those type things.</p>

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<p style="text-align: right;">Page 74</p> <p>1 But even that, the suture's absorbed. It's healed 2 up. So really you can't compare TVT mesh, or any 3 mesh for that matter, and the Burch or autologous 4 fascia for that matter. 5 Q. There's scarring when you do a Burch 6 colposuspension; correct? 7 A. Yes. By six weeks it's healed up. 8 Q. And it's not important to assess 9 whether there's any painful scarring in a Burch? 10 A. Absolutely there is, but the duration 11 of the follow-up, the perioperative morbidity is 12 extremely important. But after you've done the 13 surgery, and there's healing that's happened, 14 which 98 percent happens at six weeks, one, two, 15 five-year data is important to look at. But it's 16 not as important because you don't have the 17 progressive scarring, et cetera, that you see with 18 the polypropylenes. 19 Q. How would one go about assessing the 20 lifelong -- give me a second. 21 Can I see the exhibits. 1, 2, 3. You 22 can hold on to this one. The Burch study we 23 marked a minute ago. 24 A. Oh, I'm sorry. I took that back. 25 There you go.</p>	<p style="text-align: right;">Page 76</p> <p>1 sling, as you described. 2 MR. SNELL: Move to strike everything 3 before "it has not been done." 4 Q. BY MR. SNELL: A registry being 5 mandatory with monitoring yearly until the death 6 of all women has never been performed for the 7 Burch colposuspension; correct? 8 A. As I've mentioned already, because 9 there's no permanent device implanted in the 10 woman, it is not necessary, but to answer your 11 question, yes. 12 MR. SNELL: Move to strike everything 13 before "to answer your question, yes" as 14 nonresponsive. 15 Q. BY MR. SNELL: For any stress urinary 16 incontinence surgery that's ever been performed 17 that you are aware of, has there ever been a 18 registry conducted that was mandatory that 19 monitored every woman yearly until her death? 20 A. Unfortunately, no. And that's why 21 we're in the situation we're in now. 22 Q. Looking back at the Cochrane Review 23 you cited in your expert report -- 24 A. Yes, sir. 25 Q. -- it says in the next paragraph, "A</p>
<p style="text-align: right;">Page 75</p> <p>1 Q. Okay. That way she has it. 2 A. Okay. 3 Q. You have 5 over there? 4 A. Oh, I'm sorry. I'm taking those. 5 Q. That's okay. 6 All right. You can hold on to that 7 one. I still have some questions. 8 How would one go about conducting a 9 lifelong study on the Burch colposuspension? 10 A. A registry would be mandatory where 11 these individuals are followed. And you can't 12 have a 30 or 40 or 50 percent fallout rate. And 13 they have to be monitored on a yearly basis until 14 death. And then the true complication rate in 15 those highly experienced surgeons' hands would 16 then be known. 17 Q. And a registry being mandatory 18 monitored yearly until a woman's death has never 19 been performed for the autologous pubovaginal 20 sling; correct? 21 A. Again, for the same mentioned -- as 22 the reasons I mentioned for the Burch. There's no 23 permanent implantable device placed in that woman. 24 So the perioperative morbidity is very important, 25 but it has not been done for the pubovaginal</p>	<p style="text-align: right;">Page 77</p> <p>1 retropubic bottom-to-top route was more effective 2 than top-to-bottom route for subjective cure." 3 Do you see that? 4 A. That is what is stated, yes. 5 Q. And the TVT is the retropubic 6 bottom-to-top route; correct? 7 A. As far as I know, that is the only 8 bottom -- with the understanding -- let me back 9 up. 10 With the understanding that from my 11 understanding at this point right now, TVT is the 12 only one on the market bottom-up. So I don't know 13 if there's another one on the market. 14 Q. You have looked at the -- you looked 15 at the entire Cochrane Review from 4/2015 over -- 16 I think it's over 200 pages? 17 A. Very long document, yes. 18 Q. Right. Right. Right. And you saw 19 that the retropubic bottom-to-top studies were 20 studies that assessed the TVT retropubic device; 21 correct? 22 A. I don't recall that. Again, I have no 23 reason to doubt that. I'm just saying, there are 24 a lot of companies that used to make slings, 25 Boston Scientific, Bard, et cetera. I just don't</p>

20 (Pages 74 to 77)

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<p>1 know of another one. If that study says there's</p> <p>2 only one bottom-up and it's the TVT, I can't</p> <p>3 disagree with that. I just don't know right now.</p> <p>4 Q. You certainly know that the TVT</p> <p>5 retropubic device has been studied in more</p> <p>6 randomized control trials than any other stress</p> <p>7 urinary incontinence surgical device; correct?</p> <p>8 MR. CARTMELL: Object to the form.</p> <p>9 A. I have -- I have heard a lot of facts</p> <p>10 like that. I have never independently verified</p> <p>11 that to be true, but I don't doubt its existence.</p> <p>12 Q. BY MR. SNELL: It says the retropubic</p> <p>13 bottom-to-top route also "incurred significantly</p> <p>14 less voiding dysfunction and led to fewer bladder</p> <p>15 perforations and vaginal tape erosions"; correct?</p> <p>16 A. That is what they state, yes.</p> <p>17 Q. And those would be benefits of using a</p> <p>18 retropubic bottom-to-top route like the TVT</p> <p>19 retropubic employs as compared to a top-to-bottom</p> <p>20 route; correct?</p> <p>21 MR. CARTMELL: Object to the form.</p> <p>22 A. Well, correct except that Ethicon</p> <p>23 makes a TVT-AA, which is top-to-bottom. So based</p> <p>24 upon what they're saying here, TVT-AA would be</p> <p>25 included in the top-to-bottom. So this would be</p>	<p>1 Q. It wouldn't surprise you to learn that</p> <p>2 there were no randomized control trials on the</p> <p>3 Supris; correct?</p> <p>4 A. As I stated earlier, I was unaware of</p> <p>5 any, and hence the reason why sling data is bad.</p> <p>6 Or poor quality, let's put it that way.</p> <p>7 Q. Have you conducted an analysis of the</p> <p>8 literature regarding slings to see whether any of</p> <p>9 the other manufacturers' polypropylene slings have</p> <p>10 been subjected to more randomized control trials</p> <p>11 than the Ethicon TVT retropubic device?</p> <p>12 A. I have not done any independent</p> <p>13 research on that.</p> <p>14 Q. Have you done any PubMed searches to</p> <p>15 assess how many hundreds or thousands of studies</p> <p>16 there are on the TVT retropubic? And when I say</p> <p>17 TVT -- strike that.</p> <p>18 When I say studies, I'm not limiting</p> <p>19 it just to randomized control trials.</p> <p>20 A. I understand.</p> <p>21 Q. I mean cohort studies, studies that</p> <p>22 would comport with the level of evidence pyramid,</p> <p>23 levels 2 and 3 that you identified.</p> <p>24 MR. CARTMELL: Object to the form.</p> <p>25 A. My methodology that I use when I</p>
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<p>1 very worrisome that perhaps that TVT product</p> <p>2 employed in that fashion is actually more</p> <p>3 dangerous.</p> <p>4 Q. BY MR. SNELL: Have you ever assessed</p> <p>5 the literature on the TVT-AA device?</p> <p>6 A. There's limited data out there.</p> <p>7 Q. But have you assessed it?</p> <p>8 A. Yes, I have assessed it, and there's</p> <p>9 limited data on it.</p> <p>10 Q. And how does the voiding rates compare</p> <p>11 between the TVT retropubic and then the top-down</p> <p>12 TVT?</p> <p>13 A. The data overall with all sling</p> <p>14 products is very poor. With TVT-AA it's even</p> <p>15 worse. So I don't know. I cannot quote you a</p> <p>16 study looking at that, but I'm just saying the</p> <p>17 Cochrane analysis possibly raises the issue of a</p> <p>18 TVT-AA.</p> <p>19 Q. As you sit here today, you don't know,</p> <p>20 though whether the TVT-AA was assessed in</p> <p>21 top-to-bottom in the Cochrane Review?</p> <p>22 A. That's what I'm saying.</p> <p>23 Q. Do you know whether the Supris was</p> <p>24 assessed in this Cochrane Review?</p> <p>25 A. I don't know.</p>	<p>1 approach any of these projects is going to involve</p> <p>2 multiple different facets, but one of them is</p> <p>3 using the PubMed search engine, which is -- as far</p> <p>4 as I know, the largest search engine available,</p> <p>5 funded by the NIH. And when I search just TVT,</p> <p>6 only TVT, it comes up with about 1300 papers. But</p> <p>7 that's going to be TVT-Secur, TVT-AA, TVT -- all</p> <p>8 the TVTs.</p> <p>9 Q. BY MR. SNELL: Did you do any other</p> <p>10 search string modifiers like "tension-free vaginal</p> <p>11 tape"?</p> <p>12 A. I don't recall that --</p> <p>13 Q. TVT retropubic?</p> <p>14 A. I don't -- well, TVT is going to</p> <p>15 capture all TVTs. Tension-free vaginal tape -- I</p> <p>16 don't recall if I used that, I may have. But I</p> <p>17 searched multiple different factors looking at,</p> <p>18 you know, mesh complications associated with those</p> <p>19 things.</p> <p>20 Q. How many studies on TVT did you locate</p> <p>21 on PubMed?</p> <p>22 A. I found roughly 1300 on all TVT</p> <p>23 products, the entire product line.</p> <p>24 On just TVT retropubic or TVT classic,</p> <p>25 I can't give you a number.</p>

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<p style="text-align: right;">Page 82</p> <p>1 Q. Okay. How would the TVT retropubic 2 have less voiding dysfunction than a top-to-bottom 3 device like the Sparc that you used? 4 A. With my training in neurophysiology, 5 neuroanatomy and bladder dysfunction, it does not 6 make any intuitive sense why that difference would 7 be. You're passing a trochar up -- from bottom up 8 or top down, you should be -- there's -- the 9 voiding dysfunction should be identical. 10 There's going to be variables, such as 11 the mesh, the experience of the surgeon, the 12 amount of tension placed on it, the patient 13 factors in there. That's where the Cochrane 14 analysis -- we don't know; were the patients 15 morbidly obese; were they diabetics; their 16 previously existing bladder dysfunction. All 17 those factors I don't know. 18 Q. So I guess the answer to my question 19 then would be, you do not know how there would be 20 less voiding dysfunction seen with the TVT 21 retropubic as compared to a top-to-bottom device 22 like the Sparc; correct? 23 MR. CARTMELL: Object to the form. 24 Asked and answered. 25 A. Well, the statement, quote/unquote, I</p>	<p style="text-align: right;">Page 84</p> <p>1 incision you did when you used the Sparc? 2 A. Be 1 to 1.5 centimeters. 3 Q. And what was the other top-to-bottom 4 device you used? 5 A. The Supris. 6 Q. Supris. What was the size of the 7 vaginal incision you used with the Supris? 8 A. Same thing. 1 to 1.5 centimeters, 9 mid-urethral. 10 Q. And did you do blind passage of the 11 trochars with any of those devices? 12 A. Correct. With the Supris and the 13 Sparc, that is the identical length of blind 14 passage as with the TVT. 15 Q. And did you do blind passage with any 16 of the transobturator slings you performed? 17 A. Yes. But it's a degree -- significant 18 degree less, because you have your finger in the 19 obturator foramen. So you're passing that around 20 the obturator foramen, which is about 21 1 centimeter, but that would be blind. 22 Q. All right. You would use your finger 23 and that's known as haptic or tactile feedback; 24 correct? 25 A. I suppose. It is tactile. It's</p>
<p style="text-align: right;">Page 83</p> <p>1 don't know, implies I haven't thought about it. 2 I've thought a lot about it. It does not -- I 3 cannot come up, to answer your question, with a 4 logical explanation why that's occurring. There's 5 a variable we don't know. Is it poor quality 6 studies? Patient variables? Those issues. As I 7 mentioned earlier in the previous question. 8 Q. Okay. How is it that the TVT 9 retropubic would have less vaginal tape erosions 10 than a top-to-bottom route, such as the Sparc that 11 you use? 12 A. Well, I do not use the Sparc and 13 haven't used it for 10 years or so. Or less than 14 that. Excuse me. 15 But, again, we have to include in 16 there -- unless you can show me in the Cochrane 17 study does not include the TVT-AA, that there can 18 be some of the Ethicon product in there. 19 But to answer your question, it does 20 not make logical sense, based upon the anatomical 21 approach, to have more or less or vaginal 22 extrusions. That's why there's going to be some 23 of a variable in there that we don't know in these 24 studies. 25 Q. What was the size of the vaginal</p>	<p style="text-align: right;">Page 85</p> <p>1 feedback. Yes, you're right. 2 Q. And that's commonly done in pelvic 3 surgery? 4 A. Pelvic surgery does a lot of surgery 5 by proprioception. Yes, by feel. 6 Q. And for the autologous transobturator 7 pubovaginal sling, part of that procedure is 8 blind; correct? 9 A. No. I disagree with that because when 10 you do a different dissection, you dissect through 11 the endopelvic fascia bilaterally. You dissect 12 along the pubic bone up to the rectus muscle. 13 Then you're able to palpate from your incision in 14 the abdomen, feel right where your finger is. So 15 you pass it through the rectus muscle and then on 16 to your finger. So there's no blind passage of 5 17 to 10 centimeters like with the Sparc or the TVT. 18 Q. But there is a blind package in that 19 procedure. It's just shorter; correct? 20 A. A significant -- well, no, there's no 21 organs that can get away. That's why there's no 22 bladder perforation, or extremely rare. In my 23 experience, I've never perforated the bladder with 24 it. Where I had a 10 percent Sparc bladder 25 perforation. And you're passing it right onto</p>

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<p>1 your finger. So there's -- you know, we can</p> <p>2 splice and say, yes, there is some blind passage,</p> <p>3 but it's right onto your finger. So you're</p> <p>4 passing it through the rectus muscle. So you're</p> <p>5 talking a centimeter.</p> <p>6 Q. In the autologous pubovaginal sling</p> <p>7 placement there's blind passage performed;</p> <p>8 correct?</p> <p>9 A. I've already answered that. That's</p> <p>10 what I just stated.</p> <p>11 Q. I'm not talking about the</p> <p>12 transobturator.</p> <p>13 A. Oh, I'm sorry. You said</p> <p>14 transobturator?</p> <p>15 Q. In the autologous pubovaginal sling</p> <p>16 that you do.</p> <p>17 A. Isn't that what I just answered</p> <p>18 already?</p> <p>19 Okay. I mean, that's the same answer</p> <p>20 as what I just stated. That your finger's right</p> <p>21 up there against the rectus muscle. The needle</p> <p>22 goes right through the rectus muscle onto your</p> <p>23 finger. So there's no blind passage, like the 5</p> <p>24 to 10 centimeters like with the TVT or the Sparc.</p> <p>25 Q. I may have got confused or maybe you</p>	<p>1 in the Langer paper; correct?</p> <p>2 A. Correct.</p> <p>3 Q. And then the Kjoehede. And I'm not</p> <p>4 sure if I'm pronouncing that correct.</p> <p>5 Do you know if that's right?</p> <p>6 A. Yeah. My Swedish is not very good.</p> <p>7 But that would be reference number 9.</p> <p>8 Q. Okay.</p> <p>9 A. Correct.</p> <p>10 Q. And do you know what percent of the</p> <p>11 women were dry in follow-up in the Kjoehede study?</p> <p>12 A. I do not. I'd have to look at the</p> <p>13 study.</p> <p>14 Q. Do you know what percentage of the</p> <p>15 women were dry in follow-up of the Herbertsson</p> <p>16 study?</p> <p>17 A. No, I'd have to look at the study.</p> <p>18 Q. And I think that's spelled can</p> <p>19 H-e-r-b-e-r-t-s-s-o-n, published in Acta, A-c-t-a,</p> <p>20 Obstet Gynecol Scand, 1993, volume 72, pages 298</p> <p>21 to 301.</p> <p>22 Correct?</p> <p>23 A. That is correct, yes.</p> <p>24 Q. And looking back at the Cochrane</p> <p>25 Review that we were discussing, under the author's</p>
Page 87	Page 89
<p>1 didn't hear my earlier question right.</p> <p>2 For the autologous transobturator</p> <p>3 pubovaginal sling, that was my initial set of</p> <p>4 questions.</p> <p>5 Those involve blind passage; correct?</p> <p>6 A. That would be the same -- actually,</p> <p>7 less than with the mesh slings because we dissect</p> <p>8 deeper right underneath the muscle. So the same</p> <p>9 answer would be for the abdomen as with this.</p> <p>10 We're passing it through the obturator foramen</p> <p>11 onto your finger. So it has no chance of getting</p> <p>12 into the bladder. So if you want to define that</p> <p>13 as blind, I'll give that to you, but it's a --</p> <p>14 it's a safe passage. It's right on your finger.</p> <p>15 I'm sorry. I misunderstood your first question.</p> <p>16 MR. SNELL: It's okay. Let's take a</p> <p>17 break. We've been going for a bit. I want to use</p> <p>18 the restroom, if that's okay.</p> <p>19 MR. CARTMELL: Sure.</p> <p>20 (Recessed from 11:22 a.m. to</p> <p>21 11:41 a.m.)</p> <p>22 Q. BY MR. SNELL: Back on the record.</p> <p>23 Two of the studies you mentioned in</p> <p>24 addition to this study by Langer, L-a-n-g-e-r,</p> <p>25 were studied by Herbertsson, which is reference 8</p>	<p>1 conclusions.</p> <p>2 A. Yes, sir. Sorry.</p> <p>3 Q. You have it there?</p> <p>4 A. Yes, I do. I have both. I have my</p> <p>5 copies and then your copy.</p> <p>6 Q. Great. For the record, can we mark</p> <p>7 your copy, too, then?</p> <p>8 A. Sure.</p> <p>9 Q. Just so I can look at it at some</p> <p>10 point.</p> <p>11 (Exhibit 7 marked.)</p> <p>12 Q. BY MR. SNELL: So Exhibit 7 is your</p> <p>13 copy of this Cochrane Review by Ford, et al. we've</p> <p>14 been discussing?</p> <p>15 A. That is correct. This is the abstract</p> <p>16 off of PubMed.</p> <p>17 Q. Okay. And under the author's</p> <p>18 conclusions, it says, "mid-urethral-urethral sling</p> <p>19 operations have been the most extensively</p> <p>20 researched surgical treatment for stress urinary</p> <p>21 incontinence."</p> <p>22 You see that?</p> <p>23 A. Yes, I do.</p> <p>24 Q. And you will agree with that; correct?</p> <p>25 MR. CARTMELL: Object to the form.</p>

23 (Pages 86 to 89)

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<p style="text-align: right;">Page 90</p> <p>1 A. Again, I have no reason to doubt it. 2 But I've not done independent research on that 3 knowledge. 4 Q. BY MR. SNELL: Okay. And also it 5 says, "and have a good safety profile." 6 You would agree with that; correct? 7 MR. CARTMELL: Object to the form. 8 A. That statement needs to be taken in 9 the entirety of the paragraph, where they say 10 longer term studies are needed. But that is what 11 they state. 12 Q. BY MR. SNELL: And you agree with 13 that; correct? 14 MR. CARTMELL: Object to the form. 15 You just asked him the question. And he answered 16 it. 17 A. I agree that's what they state. And 18 then it has to be looked at in the entirety of the 19 paragraph where they say longer studies are 20 needed. 21 Q. BY MR. SNELL: And my question to you 22 is: You agree with that conclusion; correct? 23 MR. CARTMELL: Object to the form. 24 Asked and answered. 25 A. I disagree with the conclusion because</p>	<p style="text-align: right;">Page 92</p> <p>1 MR. SNELL: Stop it. Knock it off, 2 Tom. 3 MR. CARTMELL: No, I'm not. 4 MR. SNELL: Knock it off, Tom. 5 MR. CARTMELL: He answered your 6 question no. 7 MR. SNELL: No. 8 MR. CARTMELL: And I'm not going to 9 let you do this again. We're not going to sit in 10 here for seven hours where you ask the same 11 question five times because you don't like his 12 answer. 13 MR. SNELL: It's not about whether I 14 like his answer. 15 MR. CARTMELL: He told you he 16 disagrees with the conclusion. So move on. 17 MR. SNELL: No, he didn't. You're 18 misstating, Tom. 19 MR. CARTMELL: Tell him again. 20 MR. SNELL: You're giving speaking 21 objections on the record. 22 MR. CARTMELL: We're going to do this 23 once. 24 MR. SNELL: This is my question. 25 MR. CARTMELL: We're not going to do</p>
<p style="text-align: right;">Page 91</p> <p>1 longer studies have not been done. 2 Q. BY MR. SNELL: Well, you agree that 3 mid-urethral sling operations have a good safety 4 profile with the caveat that you would like to see 5 more long-term studies done; correct? 6 MR. CARTMELL: Object to the form. 7 That misstates his testimony. And I'm not going 8 to let you do this thing where you do -- you ask 9 four different times the same question, like we 10 did the last time. 11 MR. SNELL: That's fine. 12 MR. CARTMELL: He's asked -- don't 13 answer that. You've answered it three times. 14 MR. SNELL: No, he hasn't. No, he 15 hasn't. 16 MR. CARTMELL: Yes, he has. 17 MR. SNELL: No. 18 MR. CARTMELL: He answered your 19 question. You asked if he agreed with the 20 conclusion. He said no. 21 MR. SNELL: You're wrong, Tom. He 22 said not because of the caveat that it needs more 23 long-term study. So there's my follow-up 24 question, Tom. You're playing games with me. 25 MR. CARTMELL: No, I'm not.</p>	<p style="text-align: right;">Page 93</p> <p>1 it again. 2 MR. SNELL: Just knock it off. This 3 is my question. You're wasting my time. This is 4 your time you're burning here, not mine. 5 Q. BY MR. SNELL: You would agree 6 mid-urethral sling have a good safety profile with 7 the caveat that you, Dr. Elliott, would like to 8 see more long-term data on those procedures; 9 correct? 10 MR. CARTMELL: Object to the form. It 11 misstates his testimony. He's already answered 12 it. 13 A. I disagree with that. 14 Q. BY MR. SNELL: Very well. Would you 15 like to see more long-term data on the autologous 16 pubovaginal sling? 17 A. Long-term studies are always going to 18 be important. However, when we're talking about 19 safety and complications, it's comparing apples to 20 oranges because there is no medical device placed 21 in those patients that's permanent. 22 Q. Can you answer it yes or no? 23 Would you like to see more long-term 24 data on the autologous pubovaginal sling? 25 MR. CARTMELL: Objection.</p>

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<p>1 Q. BY MR. SNELL: A procedure that you</p> <p>2 perform.</p> <p>3 MR. CARTMELL: Objection. Asked and</p> <p>4 answered.</p> <p>5 A. I don't necessarily know if it is</p> <p>6 actually needed. On efficacy, I would agree with</p> <p>7 you. On safety, I disagree.</p> <p>8 Q. BY MR. SNELL: This paper you gave me</p> <p>9 by Langer on the Burch says that more longer term</p> <p>10 studies are needed on the Burch because of safety;</p> <p>11 doesn't it?</p> <p>12 A. I'd have to look at the study.</p> <p>13 Q. Here. How about we look at the very</p> <p>14 last sentence. "The most significant</p> <p>15 complications are de novo detrusor instability</p> <p>16 (16.6 percent) and anatomical defects</p> <p>17 (18.9 percent), half of which appeared only 5</p> <p>18 years postoperatively, stressing the need for</p> <p>19 long-term follow-up."</p> <p>20 A. I never denied --</p> <p>21 Q. Did I read that correctly?</p> <p>22 A. I have no reason to doubt that you --</p> <p>23 that's the editorial comment. You said the</p> <p>24 author's conclusion. So you read the editorial</p> <p>25 comment. I have it highlighted there.</p>	<p>1 which can occur, but it's not an issue of safety.</p> <p>2 Q. Those authors categorized those two</p> <p>3 issues as complications; didn't they?</p> <p>4 A. They record them as complications;</p> <p>5 that's correct.</p> <p>6 Q. Back to the Cochrane Review that you</p> <p>7 cite in your report. It says that "The</p> <p>8 mid-urethral sling-urethral slings are highly</p> <p>9 effective in the short and medium term, and</p> <p>10 accruing evidence demonstrates their effectiveness</p> <p>11 in the long-term; correct?</p> <p>12 A. That's what they state, yes.</p> <p>13 Q. And you would agree with this paper</p> <p>14 you cited in your report that mid-urethral slings</p> <p>15 are highly effective in the short and medium term?</p> <p>16 MR. CARTMELL: Object to the form.</p> <p>17 A. I will never say that the -- I will</p> <p>18 not -- I agree with you as far as effectiveness.</p> <p>19 I'm never going to be challenging the</p> <p>20 effectiveness of the TVT as far as causing -- or</p> <p>21 in treating urinary incontinence. The question is</p> <p>22 always going to be at what cost.</p> <p>23 Q. BY MR. SNELL: We can agree that the</p> <p>24 TVT retropubic device is effective in the</p> <p>25 treatment of stress urinary incontinence in women?</p>
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<p>1 Q. That's not what I read. I read this.</p> <p>2 A. Okay. Now, number one, you didn't</p> <p>3 show this what you were reading so I don't know</p> <p>4 what you're reading. I go down here, and they say</p> <p>5 longer term studies.</p> <p>6 Q. I'm not reading your highlights. I'm</p> <p>7 reading what I stated.</p> <p>8 A. Okay. That's what the author states.</p> <p>9 I'm not disagreeing with that at all.</p> <p>10 Q. So there is long-term follow-up needed</p> <p>11 on the Burch to assess safety considerations;</p> <p>12 correct?</p> <p>13 MR. CARTMELL: Objection. Asked and</p> <p>14 answered.</p> <p>15 A. They never say safety. They're</p> <p>16 talking about de novo instability and anatomical</p> <p>17 defects, which anatomical defects can occur in any</p> <p>18 woman with any type of -- as long as they have a</p> <p>19 vagina there could be prolapse happening. They're</p> <p>20 not talking safety. They're talking contraction,</p> <p>21 roping, those type of things.</p> <p>22 Q. BY MR. SNELL: They're talking safety;</p> <p>23 aren't they?</p> <p>24 A. They're talking de novo instability.</p> <p>25 Okay. That's new afterwards. Anatomical defects,</p>	<p>1 MR. CARTMELL: Object to the form.</p> <p>2 A. Correct. With the caveat, at what</p> <p>3 cost.</p> <p>4 Q. BY MR. SNELL: All right. There is no</p> <p>5 stress urinary incontinence surgery that is</p> <p>6 performed in women that is more effective than the</p> <p>7 TVT retropubic; correct?</p> <p>8 MR. CARTMELL: Object to the form.</p> <p>9 A. More effective? I would have to look</p> <p>10 at all the literature out there on pubovaginal</p> <p>11 slings, including the Burch. I would say it's</p> <p>12 safe to say that the TVT, as far as efficacy, on</p> <p>13 the average, is going to be -- specifically</p> <p>14 dealing with stress urinary incontinence</p> <p>15 recurrence, is going to be as efficacious as</p> <p>16 pubovaginal and Burch, in properly trained hands.</p> <p>17 Q. BY MR. SNELL: And you've seen a</p> <p>18 conclusion very similar to that which you stated</p> <p>19 about TVT being efficacious in the treatment of</p> <p>20 stress urinary incontinence, as compared to</p> <p>21 pubovaginal slings and the Burch in the</p> <p>22 Ogah/Cochrane Review; correct?</p> <p>23 A. That's correct. Yeah.</p> <p>24 Q. That's a paper --</p> <p>25 A. They state that that -- yeah.</p>

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<p style="text-align: right;">Page 98</p> <p>1 Q. That's a paper you reviewed; correct?</p> <p>2 A. Correct. Yes.</p> <p>3 Q. You didn't cite the Ogah review in</p> <p>4 your report. Why not?</p> <p>5 A. Because I stayed the Ford one, which</p> <p>6 is an update. So I'm not going to go back to</p> <p>7 Ogah. I'm going to go to the most updated</p> <p>8 literature.</p> <p>9 Q. Ogah compared TVT to the Burch and</p> <p>10 pubovaginal slings, though?</p> <p>11 A. Okay.</p> <p>12 Q. You're aware of that; right?</p> <p>13 A. Yeah.</p> <p>14 Q. Any reason you didn't cite that</p> <p>15 comparative data by Cochrane?</p> <p>16 A. Because that's going to be a Cochrane</p> <p>17 analysis of compiling a meta-analysis, so to</p> <p>18 speak.</p> <p>19 Q. Okay.</p> <p>20 A. So using my methodology there's going</p> <p>21 to be some papers that are not going to included</p> <p>22 and others are going to be included.</p> <p>23 Q. You would agree that there's accruing</p> <p>24 evidence that -- demonstrating the efficacy of TVT</p> <p>25 retropubic in the long-term?</p>	<p style="text-align: right;">Page 100</p> <p>1 A. You'd have to show me that study.</p> <p>2 Q. Well, it's not just one study. I'm</p> <p>3 just saying from your general awareness, are you</p> <p>4 aware that for the original TVT retropubic device</p> <p>5 it has the largest volume of longer term data</p> <p>6 compared to other manufacturers' stress</p> <p>7 incontinence mid-urethral sling devices?</p> <p>8 A. I think that's probably a fair</p> <p>9 statement, yes.</p> <p>10 Q. Have you assessed the literature to</p> <p>11 ascertain how many studies with 10 years follow-up</p> <p>12 or more exist on the TVT retropubic device?</p> <p>13 A. Have I -- I'm sorry. I'm not really</p> <p>14 following your question.</p> <p>15 Have I assessed how many 10-year</p> <p>16 studies there are?</p> <p>17 Q. 10-year or more. Yes, sir.</p> <p>18 A. I looked at the literature. I</p> <p>19 reviewed it. There are studies out there. I</p> <p>20 can't give you a number, though.</p> <p>21 Q. Are you aware if studies that look at</p> <p>22 10 years duration or more specific to the TVT</p> <p>23 retropubic device assess safety issues, such as</p> <p>24 mesh exposure or dyspareunia?</p> <p>25 A. I am unaware of any study that the</p>
<p style="text-align: right;">Page 99</p> <p>1 MR. CARTMELL: Object to the form.</p> <p>2 Are you talking just efficacy?</p> <p>3 A. Well, again, I'd have to see what</p> <p>4 you're talking about as far as which papers you're</p> <p>5 referring to. But since the product has been in a</p> <p>6 long time, naturally there's going to be longer --</p> <p>7 or hopefully there's going to be longer term</p> <p>8 studies.</p> <p>9 Q. BY MR. SNELL: You're aware there are</p> <p>10 several studies that have a duration of follow-up</p> <p>11 of seven years or more with the TVT retropubic</p> <p>12 device?</p> <p>13 A. Correct.</p> <p>14 Q. I'm not talking about other</p> <p>15 manufacturers' devices.</p> <p>16 A. Yes. There are studies out there,</p> <p>17 yes.</p> <p>18 Q. Due to your -- let me back up.</p> <p>19 I don't know if I asked you this</p> <p>20 question. If I did, I apologize.</p> <p>21 You and I can agree that with regard</p> <p>22 to long-term studies following up on a</p> <p>23 mid-urethral sling that the original TVT</p> <p>24 retropubic has the most long-term data of any of</p> <p>25 those devices?</p>	<p style="text-align: right;">Page 101</p> <p>1 primary end point is on safety with the TVT.</p> <p>2 There can be a paper here and there with large</p> <p>3 amounts of follow-up -- with large amounts of lost</p> <p>4 follow-up that can refer to an erosion or</p> <p>5 exposure.</p> <p>6 Q. So you are aware that in the longer</p> <p>7 term studies with TVT they do assess safety?</p> <p>8 A. You'd have to show me those studies.</p> <p>9 I'm sorry. Because I have to look at those</p> <p>10 studies very carefully. As I mentioned, I am not</p> <p>11 aware of any with the primary end point being on</p> <p>12 safety.</p> <p>13 Q. I didn't ask you about primary end</p> <p>14 point. I asked you about assessing safety, okay?</p> <p>15 Are you aware of TVT retropubic device</p> <p>16 studies looking at it long-term that assess</p> <p>17 safety?</p> <p>18 MR. CARTMELL: Object to the form.</p> <p>19 It's vague and ambiguous as to what you mean by</p> <p>20 assess.</p> <p>21 A. There can be random --</p> <p>22 Q. BY MR. SNELL: They look on and report</p> <p>23 about whether there were mesh erosions, mesh</p> <p>24 exposures, dyspareunia, detrusor instability.</p> <p>25 Are you aware of that?</p>

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<p>1 A. They can mention -- there are studies 2 out there that mention those various different 3 facts. They also, you know, very rarely talk 4 about contraction because it's not -- those 5 patients aren't examine. They're telephone 6 follow-ups. So, again, I'd have to look at those 7 specific studies and we can analyze that. I'm all 8 for that. But otherwise you're talking somewhat 9 vague for me.</p> <p>10 Q. What studies, long-term studies on TVT 11 are you referencing where patients were not 12 assessed?</p> <p>13 A. Well, no. I'm saying that we'd have 14 to pull out a study and look at it, how many of 15 those patients came back and had a physical exam. 16 How many of them did quality of life surveys. How 17 many of them did global bother index. And those 18 studies are very few. Hence, the reason why all 19 these different societies, the AUA, for example, 20 keep talking about moderate to low quality of 21 studies.</p> <p>22 MR. SNELL: Move to strike as 23 nonresponsive.</p> <p>24 Q. BY MR. SNELL: Admit your primary end 25 point on safety.</p>	<p>1 we're comparing apples to oranges.</p> <p>2 MR. SNELL: Move to strike everything 3 before "But to answer your question."</p> <p>4 Q. BY MR. SNELL: On the Cochrane Review 5 that you cite in your report, the last page they 6 say, referencing mid-urethral sling operations, 7 are suitable for women who have -- who are having 8 their first operation to prevent incontinence and 9 also women who have had unsuccessful surgery 10 previously.</p> <p>11 A. I'm sorry. I don't know where you 12 are.</p> <p>13 Q. Back --</p> <p>14 A. You're in the Author's conclusions?</p> <p>15 Q. Background information.</p> <p>16 A. Oh, Background.</p> <p>17 Q. It's the next page, if you flip it 18 over. Are you with me now?</p> <p>19 A. Yeah. Which paragraph are you on on 20 Background?</p> <p>21 Q. Second paragraph.</p> <p>22 A. Second paragraph starting with, "Over 23 the years"?</p> <p>24 Q. Second sentence.</p> <p>25 A. It starts, "Over the years"?</p>
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<p>1 How many Burch or pubovaginal sling 2 studies are you aware of that have long-term 3 follow-up that have a primary end point of safety?</p> <p>4 A. And you -- with -- oh, Burch or 5 pubovaginal.</p> <p>6 I'm aware of pubovaginal because 7 that's the procedure I'm doing. So I'm going to 8 be more focused on that. That have 8 to 10-year 9 follow-up where global bother index and distress 10 inventories have been obtained.</p> <p>11 Q. Right. But how many of those had a 12 primary end point of safety?</p> <p>13 A. It was part of the study. It was not 14 the primary end point.</p> <p>15 Q. Just like the TVT studies; right? It 16 was part of the study?</p> <p>17 MR. CARTMELL: Object to the form.</p> <p>18 A. Incorrect. As I've mentioned before, 19 pubovaginal slings and Burch are not a permanent 20 medical device that's implanted in a woman. 21 Therefore, the bar is changed for the pubovaginal 22 and Burch, okay.</p> <p>23 But to answer your question, I am 24 aware -- I am not aware of any primary end point 25 on safety with those other ones. But, again,</p>	<p>1 Q. Yes.</p> <p>2 A. And second sentence, "These operations 3 are suitable for women...."</p> <p>4 Okay. Yes, I see that statement. 5 Yes.</p> <p>6 Q. Would you agree that the TVT 7 retropubic device is suitable for women who are 8 having their first operation to prevent 9 incontinence?</p> <p>10 A. I disagree strongly with that unless 11 the caveat is that the woman and the physician 12 have been fully warned of all the complications 13 known.</p> <p>14 Q. A little bit further down, we were 15 talking about long-term studies. And they talk 16 about the main findings of this review.</p> <p>17 A. Under Author's conclusions?</p> <p>18 Q. Right here. We were here.</p> <p>19 A. Yeah.</p> <p>20 Q. So Main findings.</p> <p>21 A. Yes, sir.</p> <p>22 Q. So under the Main findings of the 23 review, they stated that the trial showed over 24 80 percent of women with stress urinary 25 incontinence are cured or have significant</p>

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<p style="text-align: right;">Page 106</p> <p>1 improvement in their symptoms with either 2 operation for up to five years after surgery. 3 A. Yes, I see that statement. 4 Q. Is that an accurate statement? 5 A. That is the findings of their studies. 6 Q. Do you -- 7 A. And I have never -- and as you look at 8 my expert report, ever challenged TVT's efficacy. 9 That's not an issue with me. It's at what cost. 10 Q. At the end of that paragraph it says, 11 "The evidence that we have been able to assess 12 indicates that the positive effects persist." 13 Do you see that? 14 A. Yes, I see it. 15 Q. You did not challenge that statement 16 either; correct? 17 MR. CARTMELL: Object to the form. 18 A. The evidence that they're saying is 19 they're talking about the durability of the 20 treatment for stress urinary incontinence. As I 21 mentioned, I'm not challenging that. The question 22 is at what cost. 23 Q. BY MR. SNELL: Yeah. We can agree TVT 24 retropubic -- that that device has durability for 25 treating stress urinary incontinence in women?</p>	<p style="text-align: right;">Page 108</p> <p>1 also talk about main findings pertaining to 2 adverse effects; correct? 3 A. Correct. 4 Q. And it says, "Tapes passing behind the 5 pubic bone (retropubic) seem to carry a greater 6 risk of injuring the bladder"; correct? 7 A. Oh, that is correct. 8 Q. All right. And that's been reported 9 in the literature; correct? 10 A. Yes. And that's pertaining to either 11 bottom-up, top-down. 12 Q. But even for the TVT retropubic, going 13 bottom-up, it's been known that there's a risk of 14 hitting the bladder with the trochars. That's why 15 a cystoscopy is done; correct? 16 A. That is correct. And the big question 17 then becomes the ramifications of that 18 perforation, long-term erosions and those 19 things -- erosions and extrusions, yes. 20 Q. When you did your top-down passage 21 with the mid-urethral sling, I take it you also 22 did cystoscopies as well? 23 A. Always, yes. 24 Q. I know the AUA recommends cystoscopies 25 for all incontinence procedures, surgeries, as I</p>
<p style="text-align: right;">Page 107</p> <p>1 A. Yes, I believe that the data, in my 2 clinical experience, would agree with that 3 statement. 4 Q. And that is a utility of the TVT 5 retropubic device; correct? 6 MR. CARTMELL: Object to the form. 7 It's vague and ambiguous with respect to what you 8 mean by "utility." 9 A. The device is designed specifically to 10 treat female stress urinary incontinence. 11 Q. BY MR. SNELL: Okay. 12 A. And so to answer your question then, 13 it has durable results in the long-term, but the 14 question is at what cost. 15 Q. Okay. The TVT retropubic device is 16 useful in treating female stress urinary 17 incontinence; correct? 18 MR. CARTMELL: Object to the form. 19 It's vague and ambiguous with respect to what you 20 mean by "useful." 21 A. It has been shown to be efficacious. 22 The question is at what cost. 23 Q. BY MR. SNELL: In this study -- strike 24 that. 25 In this Cochrane Review you cite, they</p>	<p style="text-align: right;">Page 109</p> <p>1 understand it. 2 Is that consistent with your 3 understanding, based upon their updated stress 4 incontinence guidelines published by Dmochowski, 5 et al.? 6 A. Dmochowski. Yeah. I don't even know 7 how to spell his name, but I know how to say it. 8 It's no problem. 9 I'd have to look at the specific 10 guidelines. For retropubic procedures, whether 11 they're top-up, bottom-down, mandatory cystoscopy. 12 Transobturator tends to be -- they say 13 they suggest it's strongly supported, but it can 14 be at the discretion of the treating physician. 15 Q. Do you do any cystoscopy when you do 16 any transobturator procedures? 17 A. I do not, no. 18 Q. You don't? 19 A. No. 20 Q. Why is that? 21 A. Because in having done 400, 500 or 22 more of those, I've never once hit the bladder, 23 because I'm dissecting right onto my finger, and I 24 bring it right out. I don't use the helical 25 trochar. Now, I've seen and taken care of a lot</p>

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<p>1 of patients with it, but I've never caused it.</p> <p>2 Q. Okay. A little further down in that</p> <p>3 paragraph in the Cochrane Review, under Adverse</p> <p>4 effects, it says, "There is moderate quality</p> <p>5 evidence that overall reported rates of</p> <p>6 tape-related complications are low, such as</p> <p>7 erosion of the tape into the vagina at about</p> <p>8 2 percent for both routes of tape insertion."</p> <p>9 Did I read that correctly?</p> <p>10 A. Yes, you did.</p> <p>11 Q. And do you agree with that?</p> <p>12 A. Disagree.</p> <p>13 Q. I didn't see in your expert report</p> <p>14 where you identify what the rate of mesh exposure</p> <p>15 was with the TVT device.</p> <p>16 A. That's because the true rate is not</p> <p>17 known.</p> <p>18 Q. I didn't see where you reported any</p> <p>19 rates of mesh exposure based on any studies for</p> <p>20 the TVT retropubic device.</p> <p>21 MR. CARTMELL: Is that a question or</p> <p>22 statement?</p> <p>23 Q. BY MR. SNELL: Am I correct, Doctor?</p> <p>24 MR. CARTMELL: We'll stipulate that</p> <p>25 that's not in there.</p>	<p>1 Q. You say these studies are done by</p> <p>2 expert high-volume surgeons.</p> <p>3 First of all, how do you define an</p> <p>4 expert high-volume surgeon?</p> <p>5 A. Well, Kuuva, et al., defined it as</p> <p>6 anybody doing -- they said the learning curve on</p> <p>7 the TVT is 15 or greater.</p> <p>8 Okay. So any -- most surgeons in the</p> <p>9 United States, based upon people sitting for the</p> <p>10 oral boards for urology, are doing 1 to 2 slings a</p> <p>11 year. Those people are not experts, but those are</p> <p>12 the people putting in the majority of slings.</p> <p>13 Okay. Now, to answer your question,</p> <p>14 how do we define an expert, it's going to be tough</p> <p>15 to say, but they're going to be doing more than</p> <p>16 that number.</p> <p>17 Q. Do you have a definition or a number</p> <p>18 in your mind, when you keep mentioning expert</p> <p>19 high-volume surgeons, what that is to you?</p> <p>20 A. It also -- because there's not a</p> <p>21 specific answer to that because it depends upon</p> <p>22 their level of training coming into the procedure</p> <p>23 or did they do a fellowship. Did they learn from</p> <p>24 an expert. Did they have Ulmsten or Nilsson come</p> <p>25 in and teach them how to do it. Those numbers are</p>
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<p>1 A. I don't believe and I don't recall</p> <p>2 stating a specific number, no.</p> <p>3 Q. BY MR. SNELL: And this Cochrane</p> <p>4 Review you cite to in your report does say that</p> <p>5 "The reported occurrence of problems with sexual</p> <p>6 intercourse including pain was low"; correct?</p> <p>7 A. That's what they state, yes.</p> <p>8 Q. And you didn't acknowledge that point</p> <p>9 in your report; did you?</p> <p>10 A. I talk about dyspareunia in there.</p> <p>11 Q. Did you acknowledge that the Cochrane</p> <p>12 Review that you cite to states that problems with</p> <p>13 sexual intercourse, including pain, were low in</p> <p>14 your report?</p> <p>15 A. I don't recall using those specific</p> <p>16 words, no.</p> <p>17 Q. Why not?</p> <p>18 A. Because, again, this is a</p> <p>19 meta-analysis of poor quality or moderate quality</p> <p>20 studies that do not focus on dyspareunia. And</p> <p>21 specifically they're short-term studies. It does</p> <p>22 not tell -- also, these are in the hands of</p> <p>23 experts, high-volume surgeons. Does not tell us</p> <p>24 the rate of the true average surgeon out there,</p> <p>25 which is known to be much higher.</p>	<p>1 going to be different than an average person who</p> <p>2 goes and has a three-hour Ethicon meeting and then</p> <p>3 goes back out in the middle of nowhere USA and</p> <p>4 puts them in. For me, I would have to say if</p> <p>5 they're not doing at least 25 or greater slings --</p> <p>6 specific sling a year, they are going to possibly</p> <p>7 be putting that patient at risk for complications.</p> <p>8 Q. Well, this study -- strike that.</p> <p>9 This Cochrane Review included 81</p> <p>10 trials. So of all the investigators in all of</p> <p>11 those 81 trials, how many of them performed at</p> <p>12 least 25 or more TVT slings in a given year?</p> <p>13 MR. CARTMELL: Do you want him to look</p> <p>14 at the underlying data and tell you that?</p> <p>15 MR. SNELL: I want him to answer my</p> <p>16 question, Tom.</p> <p>17 MR. CARTMELL: Well, but you know --</p> <p>18 A. Let's get the Cochrane analysis out</p> <p>19 and I'll look at that.</p> <p>20 MR. CARTMELL: Yeah.</p> <p>21 Q. BY MR. SNELL: Well, did you bring it</p> <p>22 here?</p> <p>23 A. No, I don't have that.</p> <p>24 Q. BY MR. SNELL: So you can't answer my</p> <p>25 question?</p>

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<p style="text-align: right;">Page 114</p> <p>1 A. Well, no, but you brought up the 2 issue. And so you have a question that I can't 3 answer based upon -- we have two pieces of paper, 4 81 studies. That should be roughly, what, 150 5 pages of data. I'd have to go through and look at 6 that. 7 Q. So as you sit here today, you can't 8 answer that? 9 A. I just answered -- I just already 10 answered that because you have not provided me 11 with the information I need. 12 Q. I asked that you bring your file to 13 this deposition. You didn't bring it. 14 A. Because with this study -- 15 MR. CARTMELL: Wait. For the record. 16 Let me just say this. You have been provided his 17 reliance list that has every single document on it 18 he reviewed and relied on. It has this 19 document that you only -- the full document. You 20 only provided a summary document. So if you 21 wanted to ask him questions about the full 22 document, you knew he reviewed it and relied on 23 it. You could have brought it. 24 MR. SNELL: Here's why, Tom, I'd like 25 him to bring his file. The document he did</p>	<p style="text-align: right;">Page 116</p> <p>1 (Exhibit 8 marked.) 2 Q BY MR. SNELL: So, Doctor, I've handed 3 you the American Urological Association's position 4 statement on the use of vaginal mesh for the 5 surgical treatment of stress urinary incontinence 6 from October 2013. 7 You're aware of this; correct? 8 A. Yes. 9 Q. And this is the same association 10 you're a member of; correct? 11 A. Yes. 12 Q. And the AUA says suburethral synthetic 13 polypropylene mesh sling placement is the most 14 common surgery currently performed for stress 15 urinary incontinence"; correct? 16 A. Yes. 17 Q. Do you know whether that statement is 18 accurate or not? 19 A. I don't know if it's accurate or not. 20 I have no reason to doubt its validity, though. 21 Q. I think you're familiar with the paper 22 by Chughtai, et al., that reports on the different 23 types of stress urinary incontinence surgeries 24 performed by urologists certifying or recertifying 25 for their boards that found the mid-urethral sling</p>
<p style="text-align: right;">Page 115</p> <p>1 produce has notes on every single page of the 2 studies. So whatever I could pull off the 3 internet or elsewhere, will not be the version 4 that he has that has his notes on it. 5 MR. CARTMELL: Okay. Now, he didn't 6 have to provide you that today. He brought it 7 with him today. I mean all you -- the rules say 8 that we got to give you is the reliance list and 9 the materials. And I've told you, I'll give you 10 the materials on a -- what do you call it? 11 MR. SNELL: Thumb drive. 12 MR. CARTMELL: Thumb drive. But you 13 have it all. You have it all. 14 MR. SNELL: I would like those with 15 his notes on them. Not your version of them. I 16 want Dr. Elliott's file. 17 MR. CARTMELL: He gave you a study 18 that has his notes on it. I don't know what he 19 has that has notes on it or not, okay? But the 20 bottom line is you have the reliance materials and 21 you know every single study and paper and internal 22 document he's relied on. 23 MR. SNELL: I don't think I know that. 24 MR. CARTMELL: Yes, you do. 25 MR. SNELL: All right. So move on.</p>	<p style="text-align: right;">Page 117</p> <p>1 to be the dominantly used procedure? 2 A. I recall the name of that study. I 3 don't recall the data. But, again, I have no 4 reason to doubt that it's the most common. But I 5 have not done independent research to verify that. 6 Q. Okay. The AUA statement says, 7 "Extensive data exist to support the use of 8 synthetic polypropylene mesh suburethral slings 9 for the treatment of female SUI." 10 A. That's what they state, yes. 11 Q. And that's an accurate statement; 12 correct? 13 MR. CARTMELL: Object to the form. 14 A. No. That's what they state. 15 Q BY MR. SNELL: I know that's what they 16 state, but that is an accurate statement; correct? 17 MR. CARTMELL: Well, is that a 18 statement by you, or are you asking him if he 19 agrees that's accurate? 20 Q. BY MR. SNELL: I'm asking you if you 21 agree that's accurate. What I just read to you. 22 MR. CARTMELL: Object to the form. He 23 just answered that question. 24 MR. SNELL: He said that's what they 25 say. I know that.</p>

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<p style="text-align: right;">Page 118</p> <p>1 A. The document, as it says now, 2 Extensive data exist to support the use of 3 synthetic polypropylene mesh suburethral slings 4 for the treatment of SUI." 5 As we've stated before, it is 6 effective, along with pubovaginal slings and 7 Burch, to treat SUI. So I agree with that. 8 Q BY MR. SNELL: Okay. 9 A. Minimal morbidity compared to the 10 alternatives, I disagree with. So I guess, I 11 can't -- 12 Q. Okay. 13 A. It's a complicated or -- not a 14 compound sentence, whatever the -- multiple 15 aspects of t the sentence. 16 Q. What Cochrane reviews or meta-analyses 17 or randomized control trials report that the TVT 18 retropubic has -- strike that. 19 When you say you disagree that the 20 mid-urethral sling have minimal morbidity compared 21 with alternative surgeries, why do you say that? 22 A. Because there have been very few 23 randomized control trials, none which are 24 long-term, comparing head-to-head autologous 25 pubovaginal slings versus TVT. The only one I can</p>	<p style="text-align: right;">Page 120</p> <p>1 When you do the autologous pubovaginal 2 slings, you do general anesthesia? 3 A. That is correct. Or spinal. 4 Q. Or spinal. And that's because that's 5 a painful procedure when you have to harvest that 6 tissue from the lady; correct? 7 A. No. You don't want them moving during 8 the procedure. 9 Q. It wouldn't be painful if that was 10 under local anesthesia? 11 A. You could do it under local. It's 12 been done under local. 13 Q. Is the autologous pubovaginal sling 14 commonly done under local anesthesia? 15 A. No, I would say it is not, no. 16 Q. Why not? 17 A. Just as I mentioned, patient's going 18 to be moving. And you'd have to inject local 19 underneath the rectus fascia. It could be done. 20 But for patient comfort, most patients don't want 21 to be awake for it. You just don't do it that 22 way. 23 Q. So when the AUA says, "Advantages 24 include, and they say anesthetic need, what do 25 they mean by that?"</p>
<p style="text-align: right;">Page 119</p> <p>1 think of off the top of my head is Amaro, et al., 2 from International Journal of Urology, I believe. 3 Q. Do you agree that with regard to the 4 TVT retropubic as compared to the pubovaginal 5 sling and the Burch that it has an advantage, 6 including shorter operative time? 7 A. It is shorter. Whether that's an 8 advantage or not -- surgeons get too caught up in 9 doing something in, say, 15 minutes. So it is 10 shorter. I'll give that to you. 11 Q. Okay. 12 A. Is it an advantage? That's debatable. 13 Q. Okay. Is it an advantage of the TVT 14 retropubic device that it can be done, if chosen, 15 locally, as compared to the Burch and the 16 pubovaginal slings? 17 A. Well, that's a difficult question. Is 18 that an advantage? I suppose in some highly 19 select patients. In all my years of doing this at 20 a high-volume tertiary center, I've never once had 21 to do a procedure under a local, as far as a 22 sling. I mean, so that's a theoretical potential 23 advantage. 24 Q. I'm not even going to ask you about 25 Burch.</p>	<p style="text-align: right;">Page 121</p> <p>1 MR. CARTMELL: Object to the form. 2 A. I suspect they're probably meaning 3 postop analgesia. 4 Q BY MR. SNELL: Is that a benefit of 5 the TVT retropubic compared to Burch and 6 pubovaginal sling? 7 A. Well, the statement they say 8 "Advantages include shorter operative time and 9 anesthetic need." 10 Q. Um-hum. 11 A. Somewhat ambiguous. I don't know if 12 they mean intraop or postop. But if you're 13 looking just at the short-term, just at the time 14 of the perioperative period, that would 15 theoretically be an advantage. But, again, it's 16 at what cost long-term. 17 Q. When you say perioperative period, 18 what are you referring to? 19 A. Meaning right before surgery, meaning 20 10 minutes before surgery, the surgery, and then 21 immediately postoperative. Like the first few 22 weeks. 23 Q. They also say, "Another advantage 24 would reduce surgical pain." 25 Do you agree that TVT retropubic has</p>

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<p>1 reduced surgical pain, and that that is an 2 advantage?</p> <p>3 A. Well, but, again, we have to go back 4 to the lack of studies. Again, I'm always aware 5 of Amaro, et al., TVT randomized versus 6 pubovaginal. In that study, hospital duration was 7 the same. And so that is debatable. But, again, 8 let's look at the short-term. I got to look at 9 long-term. As a surgeon, I got to look at 10 long-term, 10 years on down the road. So I can 11 give that to you with the caveats I mentioned.</p> <p>12 Q. So in the short-term you'd agree TVT 13 retropubic has the potential for reduced surgical 14 pain versus the Burch or the autologous 15 pubovaginal sling?</p> <p>16 MR. CARTMELL: Object to the form.</p> <p>17 A. I agree, in the immediate 18 postoperative period, let's say within the 19 first -- define that as the first six weeks of 20 surgery --</p> <p>21 Q BY MR. SNELL: Okay.</p> <p>22 A. -- especially the first week, I think 23 it's acceptable to say that the TVT would have 24 less perioperative pain than the Burch or the 25 pubovaginal sling.</p>	<p>1 RCT. So for the practice of stress urinary 2 incontinence surgery in the United States, over 3 the time period TVT retropubic device has been 4 available, would you agree that there is reduced 5 hospitalization with it compared to the autologous 6 pubovaginal sling and the Burch?</p> <p>7 A. I think there's going to be data out 8 there that supports it's a faster, quicker, and 9 less hospital stay on the average. But, again, we 10 have to look at the randomized control studies. 11 But, again, that's not an issue I'm debating. 12 It's the long-term risks that I'm talking about.</p> <p>13 Q. It says another advantage is reduced 14 voiding dysfunction.</p> <p>15 Do you believe that's a potential 16 advantage for the TVT retropubic versus the 17 autologous pubovaginal slings?</p> <p>18 MR. CARTMELL: Object to the form. 19 It's vague and ambiguous with respect to what you 20 mean by voiding dysfunction.</p> <p>21 A. Well, no, I disagree with that. I'd 22 have to say show me the -- that one very 23 specifically, you're going to need level 1 data to 24 support that. You cannot take cohort studies and 25 compare cohort to cohort. And so that one is</p>
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<p>1 Q. When you do your pubovaginal slings, 2 do you give your patients pain medicines?</p> <p>3 A. Yes.</p> <p>4 Q. Why?</p> <p>5 A. To reduce the perioperative pain.</p> <p>6 Q. How long do you give them pain 7 medications?</p> <p>8 A. We give them 10 to 15 tablets of a 9 narcotic, and they take it if they need it. They 10 stop it if they don't. So I don't know how long 11 they take it.</p> <p>12 Q. Do you agree that an advantage of the 13 TVT retropubic device is reduced hospitalization?</p> <p>14 A. Disagree.</p> <p>15 Q. Why is that?</p> <p>16 A. Based upon Amaro, et al., that 17 hospital duration was the same for the TVT and the 18 autologous pubovaginal sling.</p> <p>19 Q. Do you know of other TVT versus 20 autologous pubovaginal sling randomized control 21 trials?</p> <p>22 A. As I sit here right now, I'm not 23 aware. I'd have to go back and look at the 24 literature.</p> <p>25 Q. In general, not isolated to a single</p>	<p>1 highly debatable.</p> <p>2 Q BY MR. SNELL: When you see "voiding 3 dysfunction" -- and this is written by the 4 organization that you belong to; right?</p> <p>5 A. Oh, yeah, and I know the people who 6 wrote it. One's on staff with me.</p> <p>7 Q. When you see the term "voiding 8 dysfunction" -- Mr. Cartmell objected as vague. 9 What did the AUA mean by "voiding 10 dysfunction" in this position statement.</p> <p>11 MR. CARTMELL: Object to the form.</p> <p>12 A. Yeah, when these guys and women get 13 together, this is a big argument, because, again, 14 I know the people on this board and I'm at the 15 meetings. I don't go -- I'm not a member of this 16 and the guidelines.</p> <p>17 But voiding dysfunction can be 18 anything. Stress incontinence, overactive 19 bladder, urgency frequency, nocturnal enuresis, 20 bladder pain with urination. Voiding dysfunction 21 is very vague. And hence, the reason why Rovner, 22 et al., wrote up a follow-up article in this in 23 the AUA newsletter.</p> <p>24 Q BY MR. SNELL: Actually, Rovner's 25 follow-up was before this was reissued. You know</p>

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<p style="text-align: right;">Page 126</p> <p>1 that; right?</p> <p>2 A. This was were the --</p> <p>3 Q. October 2013.</p> <p>4 A. 2013 is the one I'm referring to.</p> <p>5 Q. This paper was issued after Rovner's</p> <p>6 commentary?</p> <p>7 A. Well, no, this is a revision of the</p> <p>8 original; wasn't it? I'd have to look at when the</p> <p>9 first one came out, and it's a revision of it.</p> <p>10 Update.</p> <p>11 Q. On the very back page, October 2013,</p> <p>12 revised. Correct?</p> <p>13 A. Yeah.</p> <p>14 Q. They state that "mesh-related</p> <p>15 complications can occur following polypropylene</p> <p>16 sling placement, but the rate of these</p> <p>17 complications is acceptably low."</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. "It is the AUA's opinion that any</p> <p>21 restriction on the use of synthetic polypropylene</p> <p>22 mesh suburethral slings would be a disservice to</p> <p>23 women who choose surgical correction of SUI."</p> <p>24 Do you see that?</p> <p>25 A. Yes, I do.</p>	<p style="text-align: right;">Page 128</p> <p>1 you have used it?</p> <p>2 A. It's going to depend upon the</p> <p>3 procedure we are discussing, but when specifically</p> <p>4 in TVT, from my perspective, based upon the</p> <p>5 literature and what's out there, as far as</p> <p>6 degradation, et cetera, anything short of lifelong</p> <p>7 is going to be insufficient.</p> <p>8 MR. SNELL: I don't think -- move to</p> <p>9 strike as nonresponsive.</p> <p>10 Q BY MR. SNELL: I'm trying to get a</p> <p>11 definition from you. So when you use the term</p> <p>12 "short-term," what do you mean by that?</p> <p>13 A. Short-term specifically relative to</p> <p>14 polypropylene meshes --</p> <p>15 Q. Okay.</p> <p>16 A. -- because it is a permanent</p> <p>17 implantable device, shown to have degradation in</p> <p>18 Klinge, et al., up to 15 years, Ethicon's</p> <p>19 statement showing that degradation continues,</p> <p>20 contraction, et cetera. Anything less than</p> <p>21 lifelong, to me, is short-term and insufficient.</p> <p>22 Q. And you like to apply a different bar</p> <p>23 to the Burch colposuspension; correct?</p> <p>24 A. Burch and also the autologous</p> <p>25 because -- specifically because those are no</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. "Multiple case series and randomized</p> <p>2 control trials attest to the efficacy of synthetic</p> <p>3 polypropylene mesh slings at 5 to 10 years."</p> <p>4 Do you see that?</p> <p>5 A. Yes, I do.</p> <p>6 Q. "The efficacy is equivalent or</p> <p>7 superior to other surgical techniques." Correct?</p> <p>8 A. That's what it states, yes.</p> <p>9 Q. And you've seen literature and data</p> <p>10 that supports that statement?</p> <p>11 A. As it pertains to efficacy, I agree.</p> <p>12 I mean, equivalent, I think is fine. And superior</p> <p>13 is debatable, and you have to look at those</p> <p>14 specific studies, but I'm not going to argue that.</p> <p>15 Q. "There is no significant increase in</p> <p>16 adverse events observed over this period of</p> <p>17 follow-up"; correct?</p> <p>18 A. Yeah. And that's the actual key right</p> <p>19 there, "over this period of follow-up," which is</p> <p>20 short-term.</p> <p>21 Q. How do you define -- did I ask you how</p> <p>22 you define "short-term"? I know you've mentioned</p> <p>23 that term.</p> <p>24 A. Yeah.</p> <p>25 Q. Can you define "short-term" for me as</p>	<p style="text-align: right;">Page 129</p> <p>1 permanent implantable device. With that said, for</p> <p>2 example, when the ProteGen sling was used in the</p> <p>3 past, the Gortex sling was used in the past, then</p> <p>4 I would say for those, you need to have lifelong</p> <p>5 follow-up.</p> <p>6 Okay. But, again, when we're talking</p> <p>7 about autologous tissue, the patient's own, or</p> <p>8 Burch, where there's no tissue used, the</p> <p>9 products -- there's no product in there to have</p> <p>10 lifelong problems with.</p> <p>11 Q. So how do you define short-term as to</p> <p>12 the autologous and the Burch?</p> <p>13 A. Well, a minimum study criteria</p> <p>14 established about four, five years ago, said any</p> <p>15 study less than 12 months for sling procedures was</p> <p>16 insufficient.</p> <p>17 So, again, it depends on what you're</p> <p>18 looking at in a study. But if we're looking at</p> <p>19 efficacy, efficacy is a different story. Efficacy</p> <p>20 can be lifelong. But if we're looking at</p> <p>21 perioperative complications, then really two years</p> <p>22 out. Patients heal. But there is no written in</p> <p>23 stone what short-term, long-term is.</p> <p>24 Q. I was just following up, though,</p> <p>25 because you used those terms, and I want to know</p>

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<p style="text-align: right;">Page 130</p> <p>1 what it means to you.</p> <p>2 So what is short-term --</p> <p>3 A. Short-term --</p> <p>4 Q. -- in the context of an autologous</p> <p>5 pubovaginal sling?</p> <p>6 MR. CARTMELL: Are you talking about</p> <p>7 in the context of a study?</p> <p>8 MR. SNELL: Not a particular study.</p> <p>9 He says short-term.</p> <p>10 Q. BY MR. SNELL: I want to know what you</p> <p>11 mean by that.</p> <p>12 A. I understand.</p> <p>13 Q. You've told me about the TVT and</p> <p>14 stuff, and I hear you. But now I want to know</p> <p>15 what standard do you apply to the Burch when you</p> <p>16 say short-term?</p> <p>17 A. Less than 12 months.</p> <p>18 Q. Okay.</p> <p>19 A. Less than 12 months. Arguably, 24</p> <p>20 months.</p> <p>21 Q. And what do you mean -- strike that.</p> <p>22 What standard do you use for the</p> <p>23 definition of short-term with regard to the</p> <p>24 autologous pubovaginal sling?</p> <p>25 A. Same thing. 12 months definitively.</p>	<p style="text-align: right;">Page 132</p> <p>1 been discussed. Ethicon knows that. So that</p> <p>2 actually is a very good point. Perhaps Prolene is</p> <p>3 not safe product, as we've been told.</p> <p>4 MR. SNELL: Move to strike as</p> <p>5 non-responsive.</p> <p>6 Q. BY MR. SNELL: My question was: It's</p> <p>7 known that permanent sutures can degrade. In</p> <p>8 fact, it's known that permanent sutures can have</p> <p>9 suture erosion if employed with the Burch</p> <p>10 colposuspension or the autologous pubovaginal</p> <p>11 sling procedure; right?</p> <p>12 A. Incorrect.</p> <p>13 Q. You haven't seen publications by</p> <p>14 people like Ed McGuire and others that report</p> <p>15 suture erosions following an autologous</p> <p>16 pubovaginal sling at an average duration follow-up</p> <p>17 of greater than 24 months?</p> <p>18 A. If you're doing a pubovaginal sling in</p> <p>19 the classic way where it's described, where the</p> <p>20 Prolene sutures are high up in the abdomen, away</p> <p>21 from the bladder, there should be zero erosions.</p> <p>22 If somebody's doing a variant of it, that's a</p> <p>23 different story. I can't speak to that. Burch is</p> <p>24 the same thing. You have a Prolene suture, which</p> <p>25 we know degrades based upon studies, okay, which</p>
<p style="text-align: right;">Page 131</p> <p>1 Arguably 24 months.</p> <p>2 Q. Okay. Is that for safety, too?</p> <p>3 A. Yes. But, again, we don't have any</p> <p>4 permanent implantable device with those other</p> <p>5 procedures. So perioperative morbidity is a more</p> <p>6 important issue.</p> <p>7 Q. Well, you know there can be permanent</p> <p>8 sutures placed at the time of the autologous</p> <p>9 pubovaginal sling or a Burch; correct?</p> <p>10 A. Yes. And those are --</p> <p>11 Q. And you know there can be suture or --</p> <p>12 MR. CARTMELL: Let him finish. Hold</p> <p>13 on? Yes, and those are?</p> <p>14 A. Yes, and those are usually Prolene</p> <p>15 sutures, which we've been told by Ethicon are</p> <p>16 safe. However, in my practice, I've had two</p> <p>17 patients develop suture granulomas; so I don't use</p> <p>18 them. I use Vicryl sutures.</p> <p>19 Q. BY MR. SNELL: And you know that</p> <p>20 suture erosion can occur with those -- any type of</p> <p>21 permanent suture; correct?</p> <p>22 A. Then that raises the very real</p> <p>23 possibility of those sutures causing degradation,</p> <p>24 inflammatory reaction, foreign body response,</p> <p>25 which we know happens in the dog model. That's</p>	<p style="text-align: right;">Page 133</p> <p>1 are outlined in my expert report. Ethicon knows</p> <p>2 it. Prolene, as a much suture, degrades. If you</p> <p>3 knot it up and put it by the bladder, you can have</p> <p>4 degradation, foreign body reaction, and then</p> <p>5 subsequently erosion. So, yes, the question is</p> <p>6 why.</p> <p>7 MR. SNELL: Move to strike as</p> <p>8 nonresponsive.</p> <p>9 Q. BY MR. SNELL: My question was: Do</p> <p>10 you know there are studies that report suture</p> <p>11 erosions by people who do the autologous</p> <p>12 pubovaginal sling, like Ed McGuire, that report</p> <p>13 suture erosions at a follow-up of greater than</p> <p>14 24 months?</p> <p>15 A. I would have to see that exact study</p> <p>16 and we'd have to review it, see how they did the</p> <p>17 study. But, again, it raises the issue of why</p> <p>18 that's occurring.</p> <p>19 Q. My question is: Do you know whether</p> <p>20 or not the data exists?</p> <p>21 A. I answered that and said I'd have to</p> <p>22 see the studies you're talking about and how they</p> <p>23 did the procedure.</p> <p>24 MR. CARTMELL: Lunch is ready when you</p> <p>25 are.</p>

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<p style="text-align: right;">Page 134</p> <p>1 MR. SNELL: Is it. Yeah, let's go 2 ahead and do lunch. 3 (Recessed from 12:30 p.m. to 4 1:01 p.m.) 5 (Exhibit 9 marked.) 6 Q BY MR. SNELL: Doctor, I've handed you 7 the Position Statement on mid-urethral 8 sling-Urethral Slings for Stress Urinary 9 Incontinence By IUGA. 10 You're familiar with this document? 11 A. Yes, I am. 12 Q. This is one of those professional 13 societies to which you belong today? 14 A. That is correct. 15 Q. And similar to the AUA statement that 16 we looked at, it talks about efficacy of the 17 mid-urethral slings; correct? 18 A. Correct. 19 Q. And it talks about safety of 20 mid-urethral slings; correct? 21 A. Yeah. It discusses it, yes. 22 Q. All right. In the third paragraph, 23 when they're talking about mid-urethral slings, 24 they state that "They have been shown to be as 25 effective as more invasive traditional surgery</p>	<p style="text-align: right;">Page 136</p> <p>1 mid-urethral slings from over 2,000 publications 2 making this treatment the most extensively 3 reviewed and evaluated procedure for female stress 4 urinary incontinence now in use." 5 Do you agree with that? 6 A. I have not looked at that. 7 Q. "These scientific publications studied 8 all types of patients, including those with 9 co-morbidities, such as prolapse, obesity, and 10 other types of bladder dysfunction." 11 Have you analyzed that? 12 A. Independently analyzed it, I've read 13 the studies concerning that. 14 Q. You haven't read all 2,000 15 publications they're referring to; correct? 16 A. No. That is correct. Yes. 17 Q. It says, "It is, however, acknowledged 18 that any operation can cause complications." 19 And that's a fair statement; correct? 20 A. There can be different sets of 21 complications, but any procedure can have 22 complications. 23 Q. "For mid-urethral slings these include 24 bleeding, damage to the bladder and bowel, voiding 25 difficulty, tape exposure and pelvic pain; all of</p>
<p style="text-align: right;">Page 135</p> <p>1 with major advantages of shorter operating and 2 admission times and a quicker return to normal 3 activities together with lower rates of 4 complications." 5 Do you see that? 6 A. Yes, I do. 7 Q. Do you disagree with the IUGA position 8 statement? 9 A. I disagree. 10 Q. "This has resulted in the mid-urethral 11 sling becoming the operation of choice in Europe, 12 Asia, South America, South Africa, Australasia," 13 A-u-s-t-r-a-l-a-s-i-a, "and North America for the 14 treatment of SUI with several million procedures 15 performed worldwide." 16 Do you see that? 17 A. Yes, I do. 18 Q. Do you agree or disagree with that 19 statement that it is the operation of choice as 20 amongst the alternative surgeries? 21 A. It is the most common procedure -- 22 Q. Okay. 23 A. -- I mean, performed. 24 Q. A little further down it says, "There 25 is robust evidence to support the use of</p>	<p style="text-align: right;">Page 137</p> <p>1 these may require repeat surgery, but this is 2 uncommon." 3 Do you see that? 4 A. Yes, I do. 5 Q. A little further down, they talk about 6 "long-term effectiveness of up to 80 percent has 7 been demonstrated in studies including one which 8 has followed up a small group of patients for 9 17 years"; correct? 10 A. That's what it states, yes. 11 Q. And in this IUGA statement has a list 12 of references -- do you have that? All right. 13 So for the 17-year study, you 14 understand that to be the Nilsson paper on the TVT 15 retropubic study? 16 A. That's the only 17-year one. I'll 17 make an argument that it's not TVT. 18 Q. What argument would you make that it's 19 not TVT? 20 A. Based upon the deposition by Arnaud 21 who said it's not a TVT product. And he doesn't 22 know if it's the polypropylene mesh even used by 23 Ethicon -- or manufactured by Ethicon. 24 Q. Do you have any -- have you done any 25 independent confirmation of whether or not that</p>

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<p style="text-align: right;">Page 138</p> <p>1 product was TVT other than what you just 2 referenced with regard to Dr. Axel Arnaud's 3 deposition testimony? 4 A. The only way I'd have access to that 5 is via the deposition. It's impossible to know 6 that in another independent source, but since Axel 7 Arnaud is very high up in Ethicon and he states 8 it's not TVT, I'm going to believe him. 9 Q. Do you know whether that mesh was a 10 Prolene -- polypropylene mesh? 11 A. It was a polypropylene mesh, as what 12 he said. Maybe made by Ethicon. Maybe made by 13 Bard. He doesn't know. 14 Q. As a result IUGA supports the use of 15 monofilament polypropylene mid-urethral slings for 16 the surgical treatment of female stress urinary 17 incontinence." 18 Do you see that? 19 A. Yes, I do. 20 Q. Do you agree or disagree with IUGA's 21 support? 22 A. Disagree. 23 Q. You've read the AUGS and SUFU 24 statement on mid-urethral slings? 25 A. Yes, I have.</p>	<p style="text-align: right;">Page 140</p> <p>1 A. Correct. In June of 2013. 2 Q. Did you have to study for that exam? 3 A. Yes, I did. 4 Q. Did part of that exam testing concern 5 polypropylene mid-urethral slings? 6 A. Yes. 7 Q. Was part of that exam concerning the 8 Burch colposuspension and the autologous 9 pubovaginal sling? 10 A. It's been two years, and I can't 11 recall exactly. I know they had Burch questions 12 and I know they had sling questions, yes. 13 Q. This says, "The polypropylene mesh 14 mid-urethral sling is the recognized worldwide 15 standard of care for the surgical treatment of 16 stress urinary incontinence." 17 Do you see that? On the first page. 18 A. Unfortunately, no, I don't see it. 19 Q. Here. 20 A. I listen to -- oh, there on the bold. 21 Yes. I see it. 22 Q. And you would agree it's within the 23 standard of care for a female urologist or a 24 pelvic floor surgeon to do a polypropylene mesh 25 mid-urethral sling like the TVT retropubic today?</p>
<p style="text-align: right;">Page 139</p> <p>1 (Exhibit 10 marked.) 2 Q. BY MR. SNELL: You don't belong to 3 AUGS, but you do belong to SUFU; right? 4 A. That -- yeah. They're sister 5 societies. So I can attend AUGS meetings as a 6 member, but I am not formally in their membership 7 role. 8 Q. SUFU has over 500 members? 9 A. I don't know the number. It's a lot. 10 Q. AUGS -- do you know whether they 11 represent more than 1,700 members? 12 A. They have a lot. They have more than 13 SUFU. 14 Q. Do you have to be a urogynecologist or 15 to have passed a subspecialty female pelvic 16 medicine or reconstructive surgery boards to be a 17 member of AUGS as opposed to SUFU? 18 A. No. You can be a member of AUGS 19 without having any credentials. To take the board 20 exam, the female pelvic medicine reconstructive 21 surgery, you just have to supply certain logs, 22 have a certain amount of volume of cases and take 23 the exam. 24 Q. You took that exam and passed it; 25 right?</p>	<p style="text-align: right;">Page 141</p> <p>1 A. It is not malpractice to do that 2 procedure. 3 Q. It, therefore, is within the standard 4 of care; correct? 5 MR. CARTMELL: Object to the form. 6 A. Well, as I said, it's not going to be 7 malpractice. It is an accepted treatment out 8 there. 9 Q. BY MR. SNELL: You've reviewed -- 10 well, let me ask you: Have you reviewed the AUA 11 stress urinary incontinence guidelines? 12 A. Yeah. It depends which year you're 13 talking about. There's 2009 and others. 14 Q. The 2009 and then the update in 2012? 15 A. Yes. Yes. 16 Q. All right. I think you pronounced the 17 lead author's name -- 18 A. Oh, Dmochowski. Call him Roger. 19 Q. For example, in those AUA stress 20 urinary incontinence guidelines, they recognize 21 mid-urethral, retropubic, trans -- they -- strike 22 that. 23 In the AUA stress urinary incontinence 24 guidelines they recognize the retropubic 25 polypropylene mid-urethral sling like the TVT</p>

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<p style="text-align: right;">Page 142</p> <p>1 retropubic as being a suitable surgical option for 2 surgeons to turn to; correct? 3 A. Yeah. Using the terminology you did, 4 it is one of the treatment options available. 5 Q. And they looked at the literature, did 6 a systematic review, and they analyzed the data on 7 mid-urethral slings, Burch, and the autologous 8 pubovaginal slings, and came to that conclusion? 9 A. Yes. They analyzed more than just 10 those, but, yes, those are some of the ones they 11 analyzed. 12 Q. Those were the main groups that they 13 reported on; correct? 14 A. I'd have to look at your question -- 15 it was, you know, retropubic, transobturator, 16 pubovaginal, and Burch. 17 Q. Right. In the AUGS/SUFU statement 18 they say, "The procedure is safe, effective, and 19 has improved the quality of life for millions of 20 women." 21 Do you see that? I'm sorry. Right 22 where we were at. 23 A. Oh, I'm sorry. Yes, I see that. 24 Q. Do you agree or disagree with 25 AUGS/SUFU?</p>	<p style="text-align: right;">Page 144</p> <p>1 MR. CARTMELL: He answered it. 2 Objection. Asked and answered. 3 We're reading it. He says that are 4 "currently available on the market, I agree with 5 you, they are all unsafe." 6 MR. SNELL: He's not agreeing with me, 7 because I didn't posit the question as "please 8 agree with me." I'm just asking his opinion. 9 Q. BY MR. SNELL: Understand. So let me 10 just -- let's just strike that and make sure we 11 get a clean Q and A. 12 Do you believe, Dr. Elliott, that all 13 of the polypropylene mesh mid-urethral slings 14 available for the treatment of female stress 15 urinary incontinence are unsafe? 16 A. I believe that all the currently 17 available mesh slings available on the market as 18 of right now and their technique are unsafe. 19 Q. You do not disagree, I take it, that 20 some women can have, following the TVT retropubic 21 placement, cure of their incontinence and 22 improvement in quality of life? 23 MR. CARTMELL: Object to the form. 24 A. It is a hypothetical individual, but 25 there are going to be studies that show, as of</p>
<p style="text-align: right;">Page 143</p> <p>1 A. Disagree. 2 Q. You disagree that the procedure is 3 effective? 4 A. No. 5 Q. Do you disagree that the procedure has 6 improved the quality of lives for millions of 7 women? 8 A. I have no way of proving that. 9 Q. You disagree the procedure is safe? 10 A. Yes. 11 Q. And do you believe that all 12 polypropylene mesh mid-urethral slings are unsafe? 13 A. That are currently available on the 14 market now, I agree with you they are all unsafe. 15 Q. Let me rephrase that. I don't think I 16 asked you to agree with me. 17 MR. CARTMELL: You did. 18 MR. SNELL: No, I didn't. I think -- 19 MR. CARTMELL: Do you disagree? 20 MR. SNELL: Disagree the procedure is 21 safe, yes. 22 Q. BY MR. SNELL: All right. My question 23 was: And do you believe that all polypropylene 24 mesh mid-urethral slings are unsafe? 25 A. Okay. All the --</p>	<p style="text-align: right;">Page 145</p> <p>1 right now, they have had -- they've reached that. 2 The question is what will happen with long-term 3 follow-up. 4 Q. BY MR. SNELL: Do you only treat 5 female stress incontinence or do you also treat 6 male stress incontinence? 7 A. I treat both female and male voiding 8 dysfunction. 9 Q. Do males have stress urinary 10 incontinence? 11 A. Following prostate surgery. Almost 12 exclusively that's what I see them for. 13 Q. Do you use any medical devices for the 14 treatment of male stress urinary incontinence? 15 A. Yes. The AMS800 -- American Medical 16 Systems 800 artificial urinary sphincter. 17 Q. And are there any lifelong registries 18 monitoring those patients? 19 A. Yes. The AMS -- American Medical 20 Systems keeps a registry of all implants. Every 21 time I do a surgery on them, they are notified, 22 and I have to fill out a summary of what I did, 23 revision, complications, et cetera. 24 Q. Do those track the patients lifelong? 25 A. Yes.</p>

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<p>1 Q. Where is that data published, if at 2 all?</p> <p>3 A. It is not published. It's at AMS. 4 American Medical Systems, which is based in 5 Minnetonka, Minnesota. And that goes back to 6 1972.</p> <p>7 (Exhibit 11 marked.)</p> <p>8 Q BY MR. SNELL: I've handed you 9 Exhibit 11. This is the AUGS -- one of the AUGS 10 position statements; correct?</p> <p>11 A. Correct. This one is on pelvic floor 12 disorders, though.</p> <p>13 Q. If you look at paragraph 5 where they 14 talk about stress urinary incontinence and mesh 15 slings.</p> <p>16 A. On page 3, I think?</p> <p>17 Q. Yes.</p> <p>18 A. I'm there.</p> <p>19 Q. It says, "Full length mid-urethral 20 slings, both retropubic and transobturator" -- and 21 just so we're clear, the TVT retropubic is a full 22 length retropubic mid-urethral sling; correct?</p> <p>23 A. I'm sorry to interrupt you. I just 24 don't know where you are -- I see the paragraph. 25 I just don't know which --</p>	<p>1 sentence?</p> <p>2 A. That is outlined in detail in my 3 expert report, going to all those various issues. 4 The extensively studied, I agree with.</p> <p>5 Safe, I disagree with, as mentioned in 6 my expert report, my clinical experience, my 7 discussion in national and international meetings.</p> <p>8 Effective relative to other treatment 9 options, I agree with. We've established that 10 already.</p> <p>11 Remains a leading treatment 12 opposition, I agree. It is common, the use. I 13 don't have a problem with that.</p> <p>14 Current gold standard of care for 15 stress urinary incontinence. Gold standard means 16 absolutely nothing to me. I don't even know what 17 that means. The term gets thrown around a lot.</p> <p>18 Is it something that is compared to?</p> <p>19 It is the best. So it is -- I agree with the 20 leading treatment option. There are other things 21 that are available that it could be compared to. 22 Burch sling or the TVT.</p> <p>23 Q. The term "gold standard," that's 24 something that you've seen commonly in the medical 25 literature; correct?</p>
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<p>1 Q. The bottom five, six lines.</p> <p>2 A. Starting --</p> <p>3 Q. Actually, the bottom three lines.</p> <p>4 That's okay.</p> <p>5 A. Starting with "Full-length," yes.</p> <p>6 Q. Okay. The TVT retropubic device is a 7 full length retropubic mid-urethral sling; right?</p> <p>8 A. Okay. I'm sorry. I was trying to 9 find where you -- I thought you were reading. I'm 10 sorry.</p> <p>11 The question was, is the 12 full-length -- well, I don't necessarily know what 13 they mean by a full length. Everything is a full 14 length, whether it's short or long, but this is 15 the longest length of mesh.</p> <p>16 Q. It says they "have been extensively 17 studied, are safe and effective relative to other 18 treatment options and remain the leading treatment 19 option and current gold standard of care for 20 stress incontinence surgery"; correct?</p> <p>21 A. That's what they state, yes.</p> <p>22 Q. Do you disagree or agree with AUGS?</p> <p>23 A. I disagree.</p> <p>24 Q. What exactly do you disagree with 25 there in that paragraph -- sorry. In that</p>	<p>1 A. It is thrown around extensively. It's 2 a bad term.</p> <p>3 Q. You've seen people refer to the 4 autologous pubovaginal sling as a gold standard; 5 correct?</p> <p>6 A. Correct.</p> <p>7 Q. You've seen people refer to the Burch 8 colposuspension as the gold standard; correct?</p> <p>9 A. Correct.</p> <p>10 Q. You've seen people refer to the TVT 11 retropubic device as a gold standard; correct?</p> <p>12 A. Correct.</p> <p>13 Q. To your knowledge or understanding, is 14 there a -- strike that.</p> <p>15 To your knowledge and understanding, 16 what does it mean to be a gold standard within the 17 art of pelvic surgery?</p> <p>18 A. It should be -- this is my 19 interpretation of it.</p> <p>20 Gold standard should be the procedure 21 that has the safest, the best, which everything 22 should be compared to. The gold standard, unlike 23 gold. Gold cannot -- the true iron -- or true 24 element cannot be replaced. Okay. Gold standards 25 have evolved.</p>

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<p style="text-align: right;">Page 150</p> <p>1 In the '90s, it was the Raz, R-a-z, 2 urethropexy. That's gone now. So gold standard 3 is a shifting thing. It's what everything should 4 be compared to because it has proven itself to be 5 the best in all factors involved. 6 Q. Back when the Raz urethropexy was 7 reported in the literature, there weren't any 8 randomized control trials in that procedure, 9 comparing it to the Burch and pubovaginal sling; 10 correct? 11 A. I'd have to look at the literature. I 12 don't recall any. 13 Q. Did people refer to, like, the Raz 14 procedure as the gold standard, not based on 15 comparative -- direct comparative data? 16 A. The gold standard relative to urinary 17 incontinence has really evolved since TVT came 18 out. And that's when there was now a comparison. 19 You had some people were for Burch, some people 20 for sling, some people for the Raz. The Raz fell 21 out. Wasn't effective. Then TVT was around. 22 Then the argument came of this gold standard. 23 But, again, it's not like you can type up a paper 24 and put in equations and come up with, oh, this 25 one's gold. It's relative.</p>	<p style="text-align: right;">Page 152</p> <p>1 correct? 2 A. That is correct. 3 Q. And have you reviewed this document 4 before? 5 A. Yes, I have. 6 Q. Okay. Were you involved in the 7 drafting of this document? 8 A. No, I was not. And the interesting 9 thing is, being a member of the female urology 10 section, I don't recognize very many of these 11 names. 12 Q. This was published in 2012; right? 13 A. Yes. 14 Q. And what they did was, using their 15 methodology, they used evidence-based medicine 16 methodology and did individual literature search 17 strategies? 18 A. Correct. For the treatment of both 19 men and women. 20 Q. Fair enough. 21 And for the treatment of stress 22 urinary incontinence in women, they concluded that 23 mid-urethral slings should be offered as the first 24 line treatment; correct? 25 A. I'd have to see where you're quoting.</p>
<p style="text-align: right;">Page 151</p> <p>1 Q. There are other procedures for stress 2 urinary incontinence that have also fallen out of 3 favor, like the MMK that you earlier referenced; 4 correct? 5 A. Correct. There are many that have 6 faded away. 7 Q. The anterior repair is another; 8 correct? 9 A. Well, I don't know if you're talking 10 about the Kennedy Kelly plication. That is still 11 done somewhat, but it's not, what you would say, 12 in the upper tier of effective treatments. 13 Q. And that would be based on randomized 14 control trial data or cohort studies? 15 A. Cohort studies. 16 MR. SNELL: Let's mark this as the 17 next one. 18 (Exhibit 12 marked.) 19 Q BY MR. SNELL: Exhibit 12 is the EAU 20 Guidelines on Surgical Treatment of stress -- 21 strike that. 22 EAU Guidelines -- let me get a better 23 question out. 24 Exhibit 12 is the EAU Guidelines on 25 Surgical Treatment of Urinary Incontinence;</p>	<p style="text-align: right;">Page 153</p> <p>1 I just don't see it in the document. The 2 document's fairly long. 3 Q. Okay. The third page, go to the 4 surgical algorithm. 5 A. Yes. 6 Q. Where you see if a person has -- a 7 woman; right? The top diagram is for treatment in 8 women; right? 9 A. Correct. 10 Q. And for stress incontinent women, 11 first line is "Offer mid-urethral sling"; correct? 12 A. Yeah. Or "consider peri-urethral 13 injections"; right. 14 Q. Right. So mid-urethral sling would be 15 a first-line surgical option for the treatment of 16 stress urinary incontinence in women, according to 17 the EAU Guidelines; correct? 18 A. Yeah. Yes. This algorithm, 19 established in 2012, that is what they offer as 20 first-line treatment. 21 Q. And they also identify the 22 mid-urethral sling as a first-line surgical option 23 if there's mixed incontinence, but the stress is 24 predominant; correct? 25 A. Yes.</p>

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<p style="text-align: right;">Page 154</p> <p>1 Q. And do you disagree with the EAU 2 Guidelines in that regard? 3 A. Yes, I do. 4 (Exhibit 13 marked.) 5 Q BY MR. SNELL: This is the Guidelines 6 on Urinary Incontinence from the EAU 2015. 7 Do you see that? 8 A. Yes, I do. 9 Q. So this is when you were in your role 10 in that pertinent group; correct? 11 A. That's correct. 12 Q. First page says, "Mid-urethral slings 13 are now the most frequently used surgical 14 intervention in Europe for women with stress 15 urinary incontinence." 16 Do you see that? 17 A. I don't see it. But I heard you read 18 it. Okay. Yes. Yes, I see it. Yes. 19 Q. And for the purpose of the guidelines, 20 they did a new meta-analysis; correct? 21 A. Correct. 22 Q. Were you consulted on these 23 guidelines? 24 A. No, I was not. 25 Q. But these are people who are in the</p>	<p style="text-align: right;">Page 156</p> <p>1 A. Yes, I do. 2 Q. ICS is another organization you belong 3 to; correct? 4 A. That is correct. 5 Q. And so they cover different 6 conditions, like overactive bladder, and then they 7 have stress urinary incontinence beginning on 8 page 12. 9 A. Yes. 10 Q. Have you seen these before? 11 A. Um-hum. Yes, I have. 12 Q. Do you use these statements with any 13 of your patients? 14 A. No. 15 Q. I know ACOG and the Urology 16 Foundation, the branch of the AUA, have patient 17 guides, publications, things like that. 18 Do you use any of those materials with 19 your patients? 20 A. We have them available for education 21 purposes. We'll go through it. But to be honest, 22 usually that's so overwhelming for the average 23 individual that we don't rely on them heavily. 24 Q. Does Mayo Clinic have its own patient 25 education handouts that you use --</p>
<p style="text-align: right;">Page 155</p> <p>1 group that you belong to? 2 A. They're in -- members of the EAU. But 3 these are not people in the subsection of female 4 urology and functional urology. And I'm on the 5 board of those. And I know some of their names, 6 but they're not sitting on the board. 7 Q. Were you even aware that these urinary 8 incontinence guidelines were published in 2015 by 9 EAU? 10 A. No. I was aware they were published. 11 I was not part of their publishing. 12 Q. Does the EAU still recognize the 13 mid-urethral polypropylene slings as a surgical 14 option to treat stress urinary incontinence? 15 A. Yes. As stated in their document, 16 they do not ban its use. 17 Q. Do they still, as of today, recognize 18 the mid-urethral polypropylene sling as being the 19 appropriate first-line surgical option? 20 A. That's what they state in the previous 21 document. I don't know about this one. 22 (Exhibit 14 marked.) 23 Q. BY MR. SNELL: So these are the fact 24 sheets by ICS published July 2013. 25 Do you see that?</p>	<p style="text-align: right;">Page 157</p> <p>1 A. Yeah. We have a -- 2 Q. -- for stress urinary incontinence? 3 That's what I'm focused on. 4 A. We have an overarching, for 5 incontinence. Within it is a subsection of stress 6 incontinence. But it's not specific just to 7 stress. 8 Q. Okay. On page 13 where they're 9 talking about -- it says, "Definitive therapy for 10 SUI is surgical." 11 A. Correct. 12 Q. You would agree with that; correct? 13 MR. CARTMELL: I'm sorry. What was 14 the question again? 15 A. Definitive area for SUI is the 16 surgical? 17 Q. BY MR. SNELL: No. Let me repeat it. 18 It's not "area." 19 This states on page 13, "Definitive 20 therapy for SUI is surgical." 21 Do you see that? 22 A. No. I see it. 23 Q. Do you agree with that? 24 A. I'd say no. It is -- surgery is an 25 option for some individuals. But some individuals</p>

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<p style="text-align: right;">Page 158</p> <p>1 with appropriate counseling do not need to have 2 surgery. So depends how you're defining 3 definitive, I suppose. There are other things 4 that work. 5 Q. Right. So pelvic floor exercises; 6 correct? 7 A. Correct. That's one of them. 8 Q. And bulking agents; correct? 9 A. Correct. 10 Q. And you're aware of data showing 11 surgical -- when you compare stress urinary 12 incontinence surgery, the efficacy of that 13 compared to those alternatives, non-surgical 14 alternatives, surgery has better results? 15 A. Correct. I agree with that. I just 16 have a problem with definitive therapy. 17 Q. Right. 18 A. It's a little too dogmatic for me. 19 Q. Okay. "Worldwide, mid-urethral slings 20 comprised of synthetic mesh have become the 21 treatment of choice for SUI." 22 And we've already discussed that; 23 right? 24 A. Ad nauseam, yes. 25 Q. "Long-term data are robust and</p>	<p style="text-align: right;">Page 160</p> <p>1 A. Yes, that is a fair statement. 2 Q. And I mean, you're a better surgeon, 3 don't you think, today than when you were coming 4 out of your fellowship; correct? 5 A. Correct. 6 Q. And part of that is because you've 7 amassed more surgical volume experience; correct? 8 A. That is one aspect of it. And I have 9 read hundreds of journal articles, attend all the 10 national and international meetings, and discuss 11 with high level colleagues. But, yes, there 12 should be progress. But individuals who don't 13 have the advantages I do, aren't necessarily going 14 to progress. They could actually worsen. 15 (Exhibit 15 marked.) 16 Q BY MR. SNELL: This is the NICE, 17 N-I-C-E, Clinical Guideline 171 issued 18 September 2013 on urinary incontinence in women. 19 Are you familiar with this? 20 A. Yes, I am. 21 Q. Turn to page 24. 22 A. Okay. 23 Q. And just as background, you're aware 24 then that in the generation of this NICE guideline 25 they searched the medical literature?</p>
<p style="text-align: right;">Page 159</p> <p>1 demonstrate durable efficacy with a very low 2 complication rate, particularly in experienced 3 hands." 4 You would agree with that? 5 MR. CARTMELL: Object to the form. 6 A. I agree with parts and disagree with 7 other parts. So in totality, I would have to say 8 I disagree. 9 Q BY MR. SNELL: What do you agree with 10 in that sentence? 11 A. Long-term -- oh, what do I agree with? 12 Sorry. 13 Q. Yes. 14 A. I think, as we established, "durable 15 efficacy," I'm okay with that. 16 And then, "particularly in experienced 17 hands," as I've stated before, more experienced 18 surgeons, the data is very clear. Arnaud even 19 admitted they're going to have better results. 20 "Very low complication rates," I 21 disagree with. Strongly. 22 Q. For any type of stress incontinence 23 surgery, we can agree that more experienced 24 surgeons are going to typically give better 25 results; right?</p>	<p style="text-align: right;">Page 161</p> <p>1 A. Yes. They have done similar to what 2 the AUA guidelines are. All these societies do 3 essentially the same thing. 4 Q. And they say for when offering -- 5 strike that. 6 They state, paragraph 1.10.3, "When 7 offering a synthetic mid-urethral tape procedure 8 surgeons should: Use procedures and devices for 9 which there is current high quality evidence of 10 efficacy and safety." 11 Do you see that? 12 A. Yes, and I agree with that statement. 13 Q. They also say use only -- "only use a 14 device that they have been trained to use." 15 Do you agree with that? 16 A. Yes, I do. 17 Q. Do you use any devices that you 18 weren't trained on? 19 A. No. 20 Q. "Use a device manufactured from type 1 21 macroporous polypropylene tape." 22 Do you agree with that? 23 A. If he's referring to the Amid type 1, 24 I disagree with that. 25 Q. Well, there's no other type 1 system</p>

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<p>1 that reports and identifies macroporous versus</p> <p>2 microporous than Amid; correct?</p> <p>3 A. There is no industry standard</p> <p>4 regarding that. However, I'm stating that Amid is</p> <p>5 archaic. So macroporous is a relative term. We</p> <p>6 have to define what macroporous is.</p> <p>7 Q. So there is no -- so macroporous means</p> <p>8 macro, large; porous, pores; correct?</p> <p>9 A. That is the literal translation of the</p> <p>10 word, yes.</p> <p>11 Q. And in the Amid classification,</p> <p>12 macroporous is defined as greater or equal to</p> <p>13 75 microns; is that correct?</p> <p>14 A. Yeah. Yeah. Greater than or equal</p> <p>15 to, yeah, that's what Amid does.</p> <p>16 Q. And that's because the cells involved</p> <p>17 in tissue ingeneration, combating bacteria are all</p> <p>18 cells that are smaller than 75 microns; correct?</p> <p>19 A. Well, I mean, it goes beyond that,</p> <p>20 that the 75 microns and be able to have the</p> <p>21 inflammatory responders, be able to perforate</p> <p>22 through that.</p> <p>23 But, again, the data shows, Ethicon</p> <p>24 agrees as stating, that it's 1,000 microns now and</p> <p>25 a minimum under strain. So what I'm saying is the</p>	<p>1 MR. CARTMELL: Let him answer.</p> <p>2 A. And I'm saying, if all that were true,</p> <p>3 we would not be sitting here with all the</p> <p>4 degradation problems and inflammatory responses.</p> <p>5 And then I know what I read with Ethicon</p> <p>6 depositions, that they all agree that is too small</p> <p>7 and that is not the standard they go by. So all</p> <p>8 I'm saying is I do not agree with this as it's</p> <p>9 stated.</p> <p>10 Q BY MR. SNELL: But my question to you</p> <p>11 is: Based on your knowledge and scientific</p> <p>12 understanding, can macrophages extend pseudopodia</p> <p>13 to try to get to bacteria in spaces less than</p> <p>14 5 microns?</p> <p>15 A. They can try, but are they successful?</p> <p>16 Q. Are they --</p> <p>17 A. And this is -- this is 75 microns when</p> <p>18 it comes out of the box. But that's not under</p> <p>19 stress. So it decreases. So, again, where</p> <p>20 they're really insufficient and where I have privy</p> <p>21 to information is not what it comes out of the</p> <p>22 box, when it's been implanted in the woman and</p> <p>23 after contraction of scarring.</p> <p>24 Q. The pore size in the mesh for TVT is</p> <p>25 much larger than 75 microns out of the box. We</p>
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<p>1 Amid is archaic, and not the standard used</p> <p>2 anymore.</p> <p>3 Q. Do any of the professional societies</p> <p>4 that you belong to state and define macroporous as</p> <p>5 anything other than that which the Amid</p> <p>6 classification states it as, greater than or equal</p> <p>7 to 75 microns?</p> <p>8 A. I have yet to see that in any of the</p> <p>9 society statements that they state that because</p> <p>10 they don't know the information I've been privy</p> <p>11 to.</p> <p>12 Q. We can agree that those inflammatory</p> <p>13 cells are all smaller than 75 microns; correct?</p> <p>14 MR. CARTMELL: Object to the form.</p> <p>15 A. Not necessarily, because some of the</p> <p>16 macrophages, especially under activated states,</p> <p>17 can be up to 80 micrometers or greater.</p> <p>18 Q BY MR. SNELL: Well, you know</p> <p>19 macrophages can enhance pseudopodia, which can get</p> <p>20 into spaces that are less than 5 microns; don't</p> <p>21 you.</p> <p>22 A. Then if all that were true --</p> <p>23 Q. Answer my question. Do you know that</p> <p>24 or not?</p> <p>25 A. I was answering your question.</p>	<p>1 can agree to that.</p> <p>2 A. Out of the box, I have seen numbers</p> <p>3 all over the board because they don't have a --</p> <p>4 there's not a circle with a diameter. There's</p> <p>5 wires or fibers going everywhere. So there's not</p> <p>6 a uniform size. So you may have one greater than</p> <p>7 75. Right next to it, you have one at 10 microns.</p> <p>8 And that's what P.A. Newell said under oath.</p> <p>9 Q. Have you ever put the TVT mesh out of</p> <p>10 the box next to a millimeter ruler and looked --</p> <p>11 A. Yes.</p> <p>12 Q. -- and seen whether the pores are</p> <p>13 larger than a millimeter?</p> <p>14 A. Absolutely, I have.</p> <p>15 Q. And those pores are larger than a</p> <p>16 millimeter out of the box; correct?</p> <p>17 A. Absolutely not. A millimeter?</p> <p>18 Q. Yes. 100 microns for a TVT.</p> <p>19 A. Out of the box. You might be able to</p> <p>20 find some, but right next to it it's not. But,</p> <p>21 again, that doesn't matter out of the box. It's</p> <p>22 when it is implanted in the woman under load.</p> <p>23 Q. Yes. But those inflammatory cells</p> <p>24 don't just go in circles; do they, sir?</p> <p>25 A. Well, there's going to be</p>

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<p style="text-align: right;">Page 166</p> <p>1 literature -- and let's go to my expert report on 2 this, on degradation and pore size. I've got the 3 literature stated from individuals like Klinge, 4 Klosterhalfen, Costello, Clave, et al., who will 5 disagree with you, that, no, that pore size is 6 insufficient to have adequate tissue incorporation 7 and prevention of the inflammation which then 8 causes degradation, et cetera. 9 Q. Klinge and those doctors were 10 assessing hernia mesh, not the TVT device in the 11 application of stress incontinence in women; 12 correct? 13 MR. CARTMELL: Object to the form. 14 A. Okay. And then -- 15 Q BY MR. SNELL: Is that a yes or no? 16 A. No. I can't answer a separate yes or 17 no because my understanding is they're doing 18 hernia meshes in the abdomen. TVT is a hernia 19 mesh being put into the vagina. So it's going to 20 be a worse of an environment because of higher 21 bacteria counts. Different types of strain. So 22 if it performs poorly in the abdomen, it's going 23 to perform worse in the vagina. 24 Q. All of the citations where you cite to 25 Klinge and those doctors in your report are in the</p>	<p style="text-align: right;">Page 168</p> <p>1 have been something very good for Ethicon to have 2 done. 3 MR. SNELL: Move to strike everything 4 up to the responsiveness about "when they" with 5 regard to TVT, no. 6 Q. BY MR. SNELL: You call him Klingel. 7 A. Klinge. 8 Q. Is it Klingel or Klinge? Because I 9 heard it all different ways. 10 MR. CARTMELL: I thought it's Klinge. 11 A. It's Klinge. 12 MR. CARTMELL: Klinge, okay. He said 13 Klinge. 14 Q BY MR. SNELL: Oh, I think he said 15 Klingel, like Chris Klingel? I just want to make 16 sure I know we're talking about the same person. 17 It's the same person; right? 18 A. Klinge, yeah. 19 Q. Okay. Look, I'm even worse than you 20 are with names, and you're pretty good with names. 21 I'm bad with them. All right. 22 MR. CARTMELL: Chris Klinge. 23 Q BY MR. SNELL: So we were looking at 24 that NICE guideline. It says down -- 25 MR. CARTMELL: NICE or NICE.</p>
<p style="text-align: right;">Page 167</p> <p>1 context of hernia; correct? 2 A. All right. Let's go to my expert 3 report on pore size, because if we're going to 4 talk about this in detail -- I spent a lot of time 5 on this, and so we can go to that. So I have it 6 down here beginning around page 18, where I 7 reference internal documents, studies, et cetera. 8 Q. None of them being TVT retropubic 9 device studies that were in women; correct? 10 A. Well, if -- 11 Q. That's a yes or no. So which one is 12 it? 13 MR. CARTMELL: No. You can answer. 14 Let him answer. You cut him off again. That's 15 twice in the last minute and a half. 16 MR. SNELL: No, no. I can say a yes 17 or no question, Tom; you know that. 18 MR. CARTMELL: So let him answer the 19 question. Go ahead. 20 MR. SNELL: It's a yes or no. 21 MR. CARTMELL: Go ahead. 22 A. They have done studies looking at the 23 hernia mesh. Have Klinge, Klosterhalfen and 24 others done it specifically with the TVT? No. 25 But I have to extrapolate the data. That would</p>	<p style="text-align: right;">Page 169</p> <p>1 Q BY MR. SNELL: That's a good one. 2 It's abbreviated NICE. 3 A. I know it. 4 Q. All right. So for the NICE guideline 5 under colposuspension, it says, "Do not offer a 6 laparoscopic colposuspension as a routine 7 procedure for the treatment of stress UI in 8 women." 9 Do you see that? 10 A. Yes, I do. 11 Q. You've never done a laparoscopic 12 Burch; right? 13 A. No, I have not. 14 Q. Why would they say that respect to the 15 laparoscopic Burch? 16 A. Well, the laparoscopic Burch is really 17 not a -- let me start over. 18 A laparoscopic Burch is not a true 19 Burch procedure. They have to modify it, and it's 20 not really even a Burch. And the success has been 21 poor with the laparoscopic procedure called the 22 laparoscopic Burch. 23 Q. Under Biological slings they say, "Do 24 not offer anterior colporrhaphy, needle 25 suspensions, paravaginal defect repair and the MMK</p>

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<p style="text-align: right;">Page 170</p> <p>1 for the treatment of stress UI."</p> <p>2 Do you see that?</p> <p>3 A. Yes, I do.</p> <p>4 Q. Is that an accurate, up-to-date</p> <p>5 statement with regard to the practice of</p> <p>6 surgically treating female stress urinary</p> <p>7 incontinence?</p> <p>8 A. This is a very simplified, infantile</p> <p>9 form of it, but anterior colporrhaphy is to treat</p> <p>10 prolapses, not incontinence.</p> <p>11 Q. Okay.</p> <p>12 A. Needle suspensions have fallen out of</p> <p>13 favor because they don't work. Paravaginal defect</p> <p>14 repair, it's, again, a prolapse repair. It's not</p> <p>15 incontinence. MMK, in the correct the high-volume</p> <p>16 surgeon's hands can have decent success with it,</p> <p>17 but that's not everybody. So I agree that it's</p> <p>18 not going to be, by any means, for the</p> <p>19 overwhelming majority of people a first-line</p> <p>20 treatment.</p> <p>21 Q. Is the MMK taught at all to residents</p> <p>22 and fellows in Mayo?</p> <p>23 A. In the GYN department it may be, but</p> <p>24 not in urology at all.</p> <p>25 Q. Do you think it's a fair statement</p>	<p style="text-align: right;">Page 172</p> <p>1 Q. I printed this out September 18th,</p> <p>2 2015. You see that at the bottom?</p> <p>3 A. Yes.</p> <p>4 Q. This is where the Mayo Clinic is</p> <p>5 talking about urinary incontinence, particularly</p> <p>6 for women; right?</p> <p>7 A. Yes.</p> <p>8 Q. And you see on the second page, Mayo</p> <p>9 Clinic.</p> <p>10 And you still work at Mayo Clinic;</p> <p>11 right?</p> <p>12 A. Correct.</p> <p>13 Q. Talks about "Sling procedures to treat</p> <p>14 stress incontinence"; correct?</p> <p>15 A. Correct.</p> <p>16 Q. And they say Mayo Clinic -- are you</p> <p>17 employed by Mayo Clinic or are you an independent</p> <p>18 contractor?</p> <p>19 A. No. I'm employed by Mayo.</p> <p>20 Q. Mayo Clinic says sling procedures and</p> <p>21 bladder neck suspension procedures are the most</p> <p>22 common surgical procedures; right? Falling into</p> <p>23 those categories?</p> <p>24 A. I don't see where you're reading from.</p> <p>25 Q. Let me withdraw. Restate it.</p>
<p style="text-align: right;">Page 171</p> <p>1 that as between GYNs versus urologists, GYNs tend</p> <p>2 to do more colposuspension procedures than</p> <p>3 urologists, like yourself tend to favor slings</p> <p>4 more?</p> <p>5 MR. CARTMELL: Object to the form.</p> <p>6 A. Colposuspension just means a vaginal</p> <p>7 prolapse repair. So that's what you're talking</p> <p>8 about. They do more prolapse than we do?</p> <p>9 Q. BY MR. SNELL: No. They do more like</p> <p>10 Burch and MMK?</p> <p>11 A. Oh, yes. Oh, okay. I see what you're</p> <p>12 saying.</p> <p>13 That would probably be a fair</p> <p>14 statement, yes.</p> <p>15 (Recessed from 1:45 p.m. to</p> <p>16 1:50 p.m.)</p> <p>17 (Exhibit 16 marked.)</p> <p>18 Q. BY MR. SNELL: Doctor, I've handed you</p> <p>19 Exhibit 16. This is from the Mayo Clinic</p> <p>20 regarding urinary incontinence.</p> <p>21 Is this the information you had</p> <p>22 earlier referenced that Mayo puts out regarding</p> <p>23 urinary incontinence?</p> <p>24 A. Well, this is on their web site, yeah,</p> <p>25 which I had no role in this.</p>	<p style="text-align: right;">Page 173</p> <p>1 MR. CARTMELL: Where's it say that?</p> <p>2 Q. BY MR. SNELL: The topic under Sling</p> <p>3 procedures to treat stress incontinence on page 2.</p> <p>4 Are you there?</p> <p>5 A. Yes.</p> <p>6 Q. All right. And Mayo Clinic, your</p> <p>7 employer, says, "Most surgical procedures to treat</p> <p>8 stress incontinence fall into two main categories:</p> <p>9 Sling procedures and bladder neck suspension</p> <p>10 procedures."</p> <p>11 A. That's what it states, but the Mayo</p> <p>12 Clinic doesn't state anything. It's a building.</p> <p>13 So this is a writer that has been hired to do</p> <p>14 this, which I had no role in, but that's what they</p> <p>15 state there.</p> <p>16 Q. Well, Mayo Clinic doesn't put</p> <p>17 unreliable information on their web site to</p> <p>18 patients; do they?</p> <p>19 A. No. Again, I'm saying, Mayo Clinic is</p> <p>20 a building. So I'm saying it's like saying the</p> <p>21 White House said something. Well, no a person</p> <p>22 said it.</p> <p>23 But I'm saying, this is what is stated</p> <p>24 on the Mayo Clinic web site.</p> <p>25 Q. Right. And it says, "During a sling</p>

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<p>1 procedure, your surgeon uses strips of synthetic</p> <p>2 mesh, your own tissue or sometimes animal or donor</p> <p>3 tissue to create a sling or 'hammock' under your</p> <p>4 urethra or bladder neck; correct?</p> <p>5 A. Correct.</p> <p>6 Q. And that's accurate; right?</p> <p>7 A. That is correct; yes.</p> <p>8 Q. Depending upon which option a surgeon</p> <p>9 chooses to offer to his or her patients; correct?</p> <p>10 A. That's correct; yes.</p> <p>11 Q. "The sling procedure that's best for</p> <p>12 you depends upon your individual situation," it</p> <p>13 says.</p> <p>14 You'd agree with that?</p> <p>15 A. Correct.</p> <p>16 Q. It's got Tension-free sling under</p> <p>17 that. You with me?</p> <p>18 A. Yes.</p> <p>19 Q. "No stitches are used to attach the</p> <p>20 tension-free sling, which is made from a strip of</p> <p>21 synthetic mesh tape"; correct?</p> <p>22 A. Correct.</p> <p>23 Q. And that's like the TVT retropubic</p> <p>24 device; correct?</p> <p>25 A. That would be one of them, but there'd</p>	<p>1 material, infection and pain."</p> <p>2 That part I agree with. But in my</p> <p>3 department, in Urology, no one uses meshes, except</p> <p>4 for me one time in the past 2-1/2 years. I cannot</p> <p>5 speak for the gynecologists. But I was not part</p> <p>6 of writing this document.</p> <p>7 Q. So you disagree with the Mayo Clinic's</p> <p>8 web site.</p> <p>9 MR. CARTMELL: Object to the form. He</p> <p>10 has already answered that question. Okay? You</p> <p>11 asked him specifically what the web site says. He</p> <p>12 said he disagrees with it. So don't answer that.</p> <p>13 Q BY MR. SNELL: How about this? A</p> <p>14 little further down it says, "A conventional sling</p> <p>15 sometimes requires a larger incision than a</p> <p>16 tension-free sling. You may need an overnight</p> <p>17 stay in a hospital and usually a longer recovery</p> <p>18 period. You may also need a temporary catheter</p> <p>19 after surgery while you heal."</p> <p>20 You agree with that; right?</p> <p>21 A. Yes.</p> <p>22 Q. Do you teach your patients for whom</p> <p>23 you do an autologous sling self-catheterization?</p> <p>24 A. No.</p> <p>25 Q. You had mentioned -- we were talking</p>
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<p>1 be a lot in that category, yes.</p> <p>2 Q. "Instead, body tissue holds the sling</p> <p>3 in place"; correct?</p> <p>4 A. Correct.</p> <p>5 Q. "Eventually scar tissue forms in and</p> <p>6 around the mesh to keep it from moving."</p> <p>7 That's correct?</p> <p>8 A. Yeah. That is part of the problem,</p> <p>9 but, yes.</p> <p>10 Q. And then they talk about retropubic</p> <p>11 and transobturator approaches that we've discussed</p> <p>12 today; right?</p> <p>13 A. Correct.</p> <p>14 Q. Then on the next page, the Mayo Clinic</p> <p>15 says, "Using surgical mesh is a safe and effective</p> <p>16 way to treat stress urinary incontinence."</p> <p>17 A. That is what --</p> <p>18 Q. You agree with that; right?</p> <p>19 A. I disagree with that.</p> <p>20 Q. So you disagree with your employer,</p> <p>21 the Mayo Clinic, that surgical mesh is a safe and</p> <p>22 effective way to treat stress urinary</p> <p>23 incontinence?</p> <p>24 A. And it says, "However, complications</p> <p>25 can occur in some women, including erosion of the</p>	<p>1 about -- strike that.</p> <p>2 We were talking about the 17-year</p> <p>3 paper by Nilsson, et al.?</p> <p>4 A. Correct.</p> <p>5 Q. And you had said you were not sure as</p> <p>6 to whether that study followed patients who had</p> <p>7 received the Prolene mesh?</p> <p>8 A. Oh, I said Arnaud was not sure, and so</p> <p>9 subsequently I'm not sure.</p> <p>10 Q. I'm not asking about Arnaud. I'm</p> <p>11 asking you.</p> <p>12 A. I was clarifying.</p> <p>13 Q. Okay. So what was your methodology in</p> <p>14 selecting that one quote out of Arnaud's multiple</p> <p>15 days of testimony?</p> <p>16 MR. CARTMELL: Object to the form.</p> <p>17 I'm not sure what you mean.</p> <p>18 A. My methodology was, in this one very</p> <p>19 straightforward. I read the deposition. They</p> <p>20 asked Arnaud questions, is this TVT, and he says,</p> <p>21 no, similar, but it is not TVT.</p> <p>22 They say, is this polypropylene</p> <p>23 Ethicon, and he says, to the effect, no it could</p> <p>24 be ours. It could be Bard's. I don't know. So</p> <p>25 methodology on this one is straightforward.</p>

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1 have him say.

2 Q. Right. The jury can ultimately hear
3 testimony and decide whatever they want to.

4 A. Correct.

5 Q. But for you as a doctor, this is
6 medical literature. Did you read this and ignore
7 it or did you not know about this?

8 A. Oh, I knew it. I knew it very well.
9 I read all these, including the 17-year one. I
10 also know that Ulmsten was paid \$400,000, which
11 Arnaud said was a conflict of interest and would
12 bias the results. I also know from other things
13 that they don't necessarily write down what the
14 truth is. All I know is the authors were getting
15 paid \$400,000 originally and are getting money,
16 save TVT. The medical director of Ethicon says, I
17 don't know if it is, maybe not, but it's not TVT.

18 Q. And you chose to go with the medical
19 director?

20 A. No, I'm keeping an open mind. I have
21 to have data to show me clearly that this was.
22 Because from my perspective from what Arnaud said,
23 who should be the authority, this is a Mediscan
24 product, and or possibly Bard mesh. So it raises
25 a major problem for me. And I am not -- if you

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1 show me -- if you have data to prove it, I would
2 love to see it.

3 Q. You mentioned the \$400,000 that
4 Ulmsten received. Why does that matter to you?

5 A. Well, conflict of interest and bias,
6 unfortunately, exists in medicine. And that's why
7 now we have to declare that. Originally we did
8 not have to declare it. During my residency you
9 didn't have to do it. Early on in staff, you
10 didn't have to do it. But because of events like
11 this, now you have to declare it.

12 So if there is money and you stand to
13 make a lot of money, there's the potential for
14 bias. I didn't say there is there. I said
15 there's a potential for it. There's clearly a
16 conflict of interest, which Arnaud agreed with me
17 on that. He said there is conflict of interest in
18 this paper. So that is important. You have to
19 read this article through that lens of potential
20 bias.

21 Q. And the same would hold true for all
22 the Vypro and other studies you cited by
23 Dr. Klinge who had a financial interest, correct,
24 in promoting that product.

25 A. You --

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<p>1 MR. CARTMELL: Wait. Object to the</p> <p>2 form. It's vague and ambiguous with respect to</p> <p>3 what product you're talking about.</p> <p>4 MR. SNELL: I said Vypro; didn't I?</p> <p>5 Q. BY MR. SNELL: You know Dr. Klinge had</p> <p>6 an interest in Vypro, don't you, Doctor?</p> <p>7 A. I do know that.</p> <p>8 Q. You know he's biased with regard to</p> <p>9 Vypro; don't you?</p> <p>10 A. No. There's a difference between</p> <p>11 conflict of interest and bias. I am stating with</p> <p>12 Nilsson and Ulmsten there is a conflict of</p> <p>13 interest. There is the potential for bias. I</p> <p>14 didn't say there was bias. And as a reviewer, I</p> <p>15 have to keep an open mind and look at that. I'm</p> <p>16 not denying at all with the Klinge, Klosterhalfen,</p> <p>17 whichever one -- I can't remember which one's</p> <p>18 which. But with Vypro, if there is a financial</p> <p>19 interest there, that is a potential for conflict</p> <p>20 of interest. If there is a conflict of interest,</p> <p>21 potential for bias.</p> <p>22 Q. All right. And you know for a fact</p> <p>23 that exists with Dr. Klinge?</p> <p>24 A. I don't know for a fact. I can't keep</p> <p>25 track of who's got what where. But if you are</p>	<p>1 together. So that's not a fair comparison. The</p> <p>2 Burch can be done -- you can get it done in a 5,</p> <p>3 6, 7-centimeter incision. Outpatient, overnight</p> <p>4 stay in the hospital. So, no, I disagree with</p> <p>5 that. There are studies out there showing longer</p> <p>6 stays. It's all over the board.</p> <p>7 Q. But you'd at least agree with the</p> <p>8 statement that the pubovaginal sling is effective</p> <p>9 but is known to have a high rate of complications,</p> <p>10 require long hospital stays, and patients often</p> <p>11 experience a significant amount of pain?</p> <p>12 MR. CARTMELL: Object to the form.</p> <p>13 A. Again, we're looking at the</p> <p>14 perioperative period. So I would agree with that,</p> <p>15 but we have to always compare it to what. Are we</p> <p>16 comparing it to TVT? Are we comparing it to the</p> <p>17 synthetics? Are we comparing it to the MMK or</p> <p>18 just any transabdominal procedure?</p> <p>19 Q. BY MR. SNELL: You would agree with</p> <p>20 the statement that mid-urethral sling procedures</p> <p>21 are much less invasive than the earlier</p> <p>22 pubovaginal sling procedures; right?</p> <p>23 A. Overall, when you're doing a</p> <p>24 comparison of synthetics to the pubovaginal or</p> <p>25 Burch, those are -- the Burch and pubovaginal</p>
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<p>1 stating for me that he has a financial interest in</p> <p>2 that, that does -- I have to be concerned about</p> <p>3 that and look at it as objectively as I can.</p> <p>4 Q. And you cited to Dr. Klinge more than</p> <p>5 10 times in your expert report; right?</p> <p>6 A. Probably. And I also cite the Nilsson</p> <p>7 and Ulmsten studies quite a bit in there, too.</p> <p>8 Those are all the body of evidence in the</p> <p>9 methodology that I have to look at is look at the</p> <p>10 potential for bias in papers.</p> <p>11 Q. Tell me if you agree or disagree with</p> <p>12 these assertions. The Burch and MMK are very</p> <p>13 invasive, often result in complications, and</p> <p>14 usually require prolonged hospital stays.</p> <p>15 A. A lot of factors. It would be easier</p> <p>16 if we go one by one or if you just want to -- if</p> <p>17 you want to take the sentence in totality, it all</p> <p>18 has to be true, I disagree with it. We can go bit</p> <p>19 by bit through it, though.</p> <p>20 Q. You would agree that Burch and MMK</p> <p>21 both are very invasive?</p> <p>22 A. I disagree. Compared to what?</p> <p>23 Q. Compared to alternative surgeries for</p> <p>24 stress urinary incontinence.</p> <p>25 A. No. Now, you've lumped MMK and Burch</p>	<p>1 slings are going to be relatively more invasive.</p> <p>2 Q. Would you agree or disagree with the</p> <p>3 statement that tension-free mid-urethral sling,</p> <p>4 like the TVT retropubic, is a significant</p> <p>5 advancement in treating stress urinary</p> <p>6 incontinence?</p> <p>7 A. Oh, yes. And early on I was very --</p> <p>8 now, again, I never used the TVT because I was</p> <p>9 described the various different fears of it. But</p> <p>10 when TVT came out, it was revolutionary. It</p> <p>11 changed the way we did things. But we didn't know</p> <p>12 what we know now. And even comparing myself to</p> <p>13 two or three years ago, my opinion has changed.</p> <p>14 So, yeah, it was touted as being revolutionary.</p> <p>15 (Discussion off the record.)</p> <p>16 (Exhibit 18 marked.)</p> <p>17 Q. BY MR. SNELL: Doctor, I've given you</p> <p>18 the Cochrane Review. This is the publication in</p> <p>19 2011.</p> <p>20 A. Correct.</p> <p>21 Q. You're familiar with this; correct?</p> <p>22 A. Yes, I am.</p> <p>23 Q. And this was the Cochrane Review where</p> <p>24 they did a comparative analysis of like the</p> <p>25 retropubic TVT versus the Burch or pubovaginal</p>

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<p>1 slings; correct?</p> <p>2 A. I see suburethral slings, open</p> <p>3 retropubic colposuspension. I don't see</p> <p>4 pubovaginal in there. I'm not saying it isn't</p> <p>5 there. I just don't see it.</p> <p>6 Q. Well, here, let's -- let me just --</p> <p>7 we'll go through it quickly. In the Results</p> <p>8 section -- I'm on the very front. They say,</p> <p>9 "Minimally invasive synthetic suburethral sling</p> <p>10 operations appeared to be as effective as</p> <p>11 traditional suburethral slings"; correct?</p> <p>12 A. Correct.</p> <p>13 Q. And when they talk about traditional</p> <p>14 suburethral slings, that would be like the</p> <p>15 autologous pubovaginal sling; correct?</p> <p>16 A. That's not nomenclature that's</p> <p>17 normally used. It's not called a suburethral</p> <p>18 sling. I would have to see what they're referring</p> <p>19 to. It's called a pubovaginal sling. It's not --</p> <p>20 suburethral slings, normal nomenclature is the</p> <p>21 synthetics.</p> <p>22 Q. On the next page where they go through</p> <p>23 the different procedures, they put the -- what I</p> <p>24 read to be the pubovaginal slings and the</p> <p>25 minimally invasive slings, like TVT, under the</p>	<p>1 recall seeing another meta-analysis. And, again,</p> <p>2 then I'd have to look at how long the follow-up</p> <p>3 is. Is it 12 months or is it 30 years. That's</p> <p>4 what matters to me, end of the patient.</p> <p>5 Q. "Minimally invasive synthetic slings</p> <p>6 appeared to be as effective as the open retropubic</p> <p>7 colposuspension."</p> <p>8 A. Yeah. I don't see where you are. And</p> <p>9 I wouldn't challenge --</p> <p>10 Q. I wouldn't mislead you. I'm just</p> <p>11 reading --</p> <p>12 A. No. I don't doubt. That's what we've</p> <p>13 been discussing all along. The Burch and the</p> <p>14 pubovaginal sling and the TVT have many studies</p> <p>15 showing they have similar efficacy.</p> <p>16 Q. And here's what I want to ask you</p> <p>17 about.</p> <p>18 But the TVT retropubic sling "has</p> <p>19 fewer perioperative complications, less</p> <p>20 postoperative voiding dysfunction, shorter</p> <p>21 operative time and hospital stay, but</p> <p>22 significantly more bladder perforations."</p> <p>23 A. Correct. And the key with that</p> <p>24 statement, as you read it, was perioperative. So</p> <p>25 that's immediate perioperative. And I'm not going</p>
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<p>1 category of suburethral slings.</p> <p>2 Do you see that?</p> <p>3 A. Yeah. What they're doing is they're</p> <p>4 comparing it to the colposuspension, which would</p> <p>5 be probably supra urethral slings -- or</p> <p>6 supra urethral suspension. That's probably what</p> <p>7 they're doing.</p> <p>8 Q. Okay. But they found that "the</p> <p>9 minimally invasive synthetic suburethral slings</p> <p>10 appeared to be as effective as the traditional</p> <p>11 suburethral slings, but with shorter operating</p> <p>12 time and less postoperative voiding dysfunction</p> <p>13 and de novo urgency symptoms; correct?</p> <p>14 A. Okay. That's what they state, yes.</p> <p>15 Q. And have you seen data consistent with</p> <p>16 that conclusion by this Cochrane Review?</p> <p>17 A. I've seen data consistent with it and</p> <p>18 inconsistent with it. So, again, I'd have to</p> <p>19 analyze each of the studies, what they're talking</p> <p>20 about.</p> <p>21 Q. Have you seen any other meta-analyses</p> <p>22 that report that for the TVT retropubic compared</p> <p>23 to pubovaginal slings, it has a higher rate of</p> <p>24 complications?</p> <p>25 A. Again, I'd have to see the -- I don't</p>	<p>1 to challenge. I think it's going to be somewhat</p> <p>2 of a relative issue. It's the long-term</p> <p>3 complications that I'm most concerned about and</p> <p>4 see on a daily basis in my clinic.</p> <p>5 Q. So in the comparative studies for like</p> <p>6 comparing to the Burch, there are some</p> <p>7 perioperative complications that appear to be</p> <p>8 higher with Burch as compared to the TVT; correct?</p> <p>9 A. Correct.</p> <p>10 Q. Bladder perforation being the one</p> <p>11 higher with the TVT because of the retropubic</p> <p>12 passage; correct?</p> <p>13 A. Correct.</p> <p>14 Q. A little further down they say that</p> <p>15 the "retropubic bottom-to-top route was more</p> <p>16 effective than the top-to-bottom route"; correct?</p> <p>17 A. That was their conclusion. It says</p> <p>18 effective in -- it doesn't say exactly here, but I</p> <p>19 assume they're talking about stress urinary</p> <p>20 incontinence. That's what they state.</p> <p>21 Q. That's consistent with the Ford paper</p> <p>22 you cited; right?</p> <p>23 A. Yes.</p> <p>24 Q. And the approach used by TVT</p> <p>25 retropubic "incurred significantly less voiding</p>

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<p style="text-align: right;">Page 190</p> <p>1 dysfunction, bladder perforations, and tape 2 erosions"; correct? 3 A. That's what they state, yes. 4 Q. That's consistent with the Ford paper; 5 right? 6 A. I'd have to look back at that, but it 7 sounds similar. 8 Q. "Monofilament tapes had significantly 9 higher objective cure rates compared to 10 multifilament tapes and fewer tape erosions." 11 Do you see that? 12 A. Yes. 13 Q. And TVT is a monofilament tape; 14 correct? 15 A. Correct. 16 Q. And that's a benefit of monofilament 17 tapes over multifilament tapes, where they have 18 fewer erosions; correct? 19 A. Yeah. The multifilament is going to 20 be a worse product. Doesn't mean monofilament is 21 safe. It just says is safer relative to the worst 22 product. Worse -- 23 Q. And the -- I'm sorry. You're going -- 24 A. No, no, no, no. 25 Q. And the monofilament tape had a rate</p>	<p style="text-align: right;">Page 192</p> <p>1 Let's see here. There's Kuhn, et al. 2 Q. Let me see where you're at. 3 A. Which is a TVT paper. Let me see 4 where Kuhn is referenced. I'd have to search for 5 it. 6 Q. Just so I'm on the same page as you, 7 Doctor, I appreciate you telling me what page of 8 your report you're on where you discuss 9 contraction with the TVT. I'm going to let you -- 10 let's take a quick break. 11 (Recessed from 2:17 p.m. to 12 2:28 p.m.) 13 Q BY MR. SNELL: All right. Okay, 14 Doctor, before we took a break, I asked you to 15 show me in your expert report where you discuss 16 contraction rates with regard to the TVT device 17 and its use in women for stress urinary 18 incontinence. 19 Can you point me to that? 20 A. Well, in the Contraction section, 21 obviously we do a lot of discussion about 22 contraction, various different studies with it. 23 When we limit it specifically to TVT, I think we 24 have to look at Wang, et al., on page 24, where 25 we're talking about infections, erosions and</p>
<p style="text-align: right;">Page 191</p> <p>1 of erosion of 1.3 percent; correct? 2 A. Based upon their analysis here in the 3 hands of experts and short-term follow-up, yes, 4 that's the number they found. 5 Q. Were you aware of this Ogah/Cochrane 6 Review at the time you wrote your draft -- your 7 expert report? 8 A. I don't recall when I became aware of 9 it. It's a -- it's a well-known paper. 10 Q. In looking at your report, I did not 11 see you citing to any TVT retropubic device 12 literature where the device had been used to treat 13 stress urinary incontinence in women and where it 14 was reported that there was contraction. 15 Is that a fair statement with regard 16 to your report? 17 A. No. That would be incorrect. 18 Q. Where in your report do you report 19 studies in TVT in women that reports contractions? 20 A. Well, wherever there is pain, wherever 21 there is extrusion, that is evidence of 22 contraction. 23 Q. Where in your report do you report 24 that? 25 A. Well, if we go to pain or dyspareunia.</p>	<p style="text-align: right;">Page 193</p> <p>1 exposures, because the complication of contraction 2 is intimately tied to also exposures and 3 infections. 4 Q. So TVT and contraction -- strike that. 5 So for TVT contraction in women, you 6 point me to Wang on page 24? 7 A. That's when you specifically limit it 8 just to the TVT product. 9 Q. Right. 10 A. Because as I mentioned, all 11 complications are all intertwined. So exposure, 12 infection is intertwined with inflammation, 13 contraction, degradation, et cetera. 14 Q. And the other part of your report 15 where you talk about contraction, you talk about 16 Klinge and his discussion of hernia mesh 17 contraction; right? 18 A. That is correct, because that is a TVT 19 mesh implanted via the abdominal route. 20 Q. All right. It's not cut to and 21 configured as TVT is; correct? 22 A. No. But without -- no, you are 23 correct. However, the TVT mesh has different 24 forces placed upon it that the hernia meshes do 25 not, i.e., you can make hernia meshes lay flat.</p>

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<p style="text-align: right;">Page 194</p> <p>1 You can't do that with the vagina.</p> <p>2 Q. The hernia mesh does not have a sheath</p> <p>3 on it; correct?</p> <p>4 A. No. It does not, but it's also not</p> <p>5 placed in the vagina to have bacterial</p> <p>6 contamination.</p> <p>7 Q. When you say bacterial contamination,</p> <p>8 you're not referring to infection; are you?</p> <p>9 A. I'm referring to bacterial</p> <p>10 contamination.</p> <p>11 Q. Right. There is a difference between</p> <p>12 bacterial contamination and infection; correct?</p> <p>13 A. Yes, but infection starts with a</p> <p>14 contamination.</p> <p>15 Q. Right. You're aware of the paper by</p> <p>16 Pat Culligan where they found and they quantified</p> <p>17 the different bacteria counts in the vagina?</p> <p>18 A. Correct.</p> <p>19 Q. In that study there were patients who</p> <p>20 received the TVT as well; correct?</p> <p>21 A. I'd have to look at it. I don't</p> <p>22 recall the specifics.</p> <p>23 Q. Would it surprise you to learn that</p> <p>24 there were no infections with the TVT mesh in the</p> <p>25 Culligan paper.</p>	<p style="text-align: right;">Page 196</p> <p>1 Q. And you have not stated in your report</p> <p>2 the rate at which clinical infections occur with</p> <p>3 TVT; have you?</p> <p>4 A. I don't recall that specific, but the</p> <p>5 way you phrase it, specifically mentioned in</p> <p>6 there.</p> <p>7 Q. I have not seen in your expert report</p> <p>8 where you calculate and state the complication</p> <p>9 rates with the TVT retropubic device.</p> <p>10 A. Because we don't know the true</p> <p>11 complication rate. We can quote studies, as I</p> <p>12 mentioned, in high volume surgeons with limited</p> <p>13 follow-up. We can quote those. But as I said, we</p> <p>14 don't know the true complication rate.</p> <p>15 Q. Well, there are meta-analyses, and</p> <p>16 we've gone through a couple of them today and</p> <p>17 various other studies that report rates of</p> <p>18 complications, and you're aware of that; correct?</p> <p>19 A. Yes. But that does not reflect what</p> <p>20 is happening out in the real world and what I see</p> <p>21 in my daily practice. That the average low-volume</p> <p>22 surgeon, who does the majority of the TVTs in the</p> <p>23 United States, that's what -- you know, because</p> <p>24 Arnaud even admitted, their complication rates are</p> <p>25 even going to be higher. So, yes, we can quote</p>
<p style="text-align: right;">Page 195</p> <p>1 MR. CARTMELL: Object to the form.</p> <p>2 A. I would have to look at the</p> <p>3 methodology, because methodology is very</p> <p>4 important. I'd have to look at how they did the</p> <p>5 study and what they looked at.</p> <p>6 Q BY MR. SNELL: Have you looked at</p> <p>7 that?</p> <p>8 A. Yes, I have, but I don't have it off</p> <p>9 the top of my head.</p> <p>10 Q. Is it your opinion that whenever mesh</p> <p>11 is placed through the vagina there is bacteria</p> <p>12 that gets on it?</p> <p>13 A. We know that the vagina's impossible</p> <p>14 to sterilize, and so when you place it through the</p> <p>15 vagina, you are going to have contact with that.</p> <p>16 So it's even with the sheath on it, but then when</p> <p>17 you remove the sheath, there's going to be issues</p> <p>18 there. So the risk for contamination on every</p> <p>19 single one is definitely there.</p> <p>20 Q. But that does not translate into</p> <p>21 infection?</p> <p>22 A. It might not translate into a clinical</p> <p>23 infection/abscess, but it can correlate to a</p> <p>24 subclinical infection, leading to inflammation,</p> <p>25 degradation, and that cascade.</p>	<p style="text-align: right;">Page 197</p> <p>1 extensively the studies that you've done that show</p> <p>2 these various different complication rates with</p> <p>3 short-term follow-up and highly experienced</p> <p>4 surgeons.</p> <p>5 Q. In the studies that report on the TVT</p> <p>6 retropubic device, what percentage of those</p> <p>7 studies involved surgeons who were of average</p> <p>8 quality?</p> <p>9 A. Well, I can't speak to quality. All</p> <p>10 we can speak to is volume.</p> <p>11 Q. How many of those then had average</p> <p>12 volume for the TVT retropubic studies?</p> <p>13 A. Most likely very few of those had</p> <p>14 small volume. And the Kuuva study, they</p> <p>15 eliminated the lower volume studies -- lower</p> <p>16 volume people. So they falsely raised their</p> <p>17 success rate and lowered their complication rate.</p> <p>18 But, no, small volume surgeons aren't going to</p> <p>19 publish anything because they're small volume.</p> <p>20 MR. SNELL: Move to strike.</p> <p>21 Q. BY MR. SNELL: Do you know of all the</p> <p>22 TVT retropubic device studies which percent of</p> <p>23 them included surgeons that had average volume or</p> <p>24 less?</p> <p>25 MR. CARTMELL: Object to the form.</p>

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<p>1 Asked and answered. He said a very small 2 percentage of those. He answered your question. 3 He also said other information, but he 4 specifically answered your question. So please 5 move on. 6 Q BY MR. SNELL: Is that correct; you 7 believe it's a very small number? 8 A. Average or low-volume surgeons aren't 9 going to have their data included because they 10 don't have enough data to analyze. 11 The only way I can answer your 12 question is Kuuva, et al., where they actually 13 eliminated the small volume surgeons who had done 14 less than 15. 15 Q. I'm familiar with the Kuuva paper. 16 I'm talking about the hundreds of other TVT 17 retropubic papers. In those, is it correct that 18 you don't know what percent of those papers 19 reported on surgeons who had average to low 20 volume? 21 MR. CARTMELL: Objection. Asked and 22 answered. You can tell him again. 23 A. As I stated, my opinion is it's going 24 to be a very, very small number of small volume 25 surgeons are going to be included in those</p>	<p>1 analysis by which you segregated the investigators 2 who had low to average surgical volume as compared 3 to more than that? 4 A. I have reviewed the literature 5 extensively. Can I quote to a certain specific 6 paper? No. If you have one, show me, and I'll 7 keep an open mind and modify my statement. But 8 this is based upon experience. Again, national, 9 international meetings. Editor -- or reviewer of 10 15 different journals. And I'm reading these 11 papers constantly. And you're not seeing 12 low-volume surgeons produce papers. The only one 13 that comes close to it is Anger, et al., which 14 demonstrated that low-volume surgeons had higher 15 complication rates. 16 Q. Do you believe lower-volume surgeons 17 with other stress incontinence surgeries, like the 18 Burch or pubovaginal slings, have higher 19 complication rates? 20 A. I would think that would be true. And 21 those surgeons usually don't do those surgeries 22 because they are more complicated surgeries to 23 perform. It takes more talent to do. So most of 24 those surgeons don't do it. That was the 25 revolutionary aspect of TVT because it opened up</p>
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<p>1 studies, if any, because you don't write up a 2 paper if you've done 10. No one's going to get 3 accepted. 4 Q BY MR. SNELL: Well, you wrote up a 5 paper where you did 10 transobturator procedures? 6 A. Absolutely I did, and that was called 7 a feasibility study. In properly counseled 8 patients. I am not out there touting that that is 9 the new gold standard. That's why we called it a 10 feasibility study. 11 Q. Other than the Kuuva paper, what are 12 you relying on for that statement that it would be 13 a very, very small number? 14 A. Based upon my experience and 15 attendance at national and international meetings, 16 working at a tertiary care center, working on the 17 journal articles from 15 different journals, that 18 small volume surgeons don't write papers because 19 there's nothing there to publish. So, therefore, 20 my experience is, and I'll state unequivocally, 21 very, very small percentage. If you want a 22 number, 1 to 2 percent, if that. And they're not 23 going to get published anywhere. 24 Q. Have you surveyed the literature for 25 all the TVT retropubic device studies and done an</p>	<p>1 minimal -- it opened up stress incontinence 2 surgery to the common surgeon. 3 Q. Is the common surgeon unqualified in 4 your opinion to do TVTs? 5 A. The common surgeon needs to -- no, the 6 common surgeon -- let's be careful on the word 7 "common." I'm saying the average, private 8 practice surgeon, who is doing less than 15 or so 9 a year, based upon the Kuuva study, et al., is 10 going to be having a higher complication rate. 11 Most of these studies also demonstrate in highly 12 experienced hands. 13 So I'm saying as far as the common, 14 the average surgeon out there, they are not going 15 to have the expertise of the high-volume surgeons; 16 hence, complications go up. 17 Q. Do you believe that surgeons in 18 private practice have less surgical skills than 19 surgeons in universities? 20 A. Absolutely not. It just depends upon 21 their experience. There are some that I know in 22 private practice who do very high volumes. It's 23 not an issue of the specific individual. It's an 24 issue of their volumes. And you know if you look 25 at the Nilsson study, Nilsson is a five-year</p>

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<p>1 study. That was -- five-year study? Yeah. It's</p> <p>2 a five-year study.</p> <p>3 See, they very clearly -- all surgeons</p> <p>4 involved were experienced urogynecologists well</p> <p>5 trained in TVT surgery. That's not going to be</p> <p>6 your average surgeon. That's are highly qualified</p> <p>7 people.</p> <p>8 Q. How many average pelvic surgeons in</p> <p>9 the United States use TVT?</p> <p>10 A. I can't answer that question. I don't</p> <p>11 know the -- a way of referencing it. We'd have to</p> <p>12 look at ethical sales and where they go to and the</p> <p>13 volumes that move off the shelf. That data would</p> <p>14 be available.</p> <p>15 Q. Have you analyzed that data?</p> <p>16 A. That data's been tried to get and</p> <p>17 can't.</p> <p>18 Q. How many high-volume surgeons are</p> <p>19 there in the United States for TVT retropubic</p> <p>20 device as you define high volume?</p> <p>21 A. There's going to be a certain number.</p> <p>22 But I don't know what that number would be.</p> <p>23 Around the nation there's going to be people that</p> <p>24 are going to be very good surgeons.</p> <p>25 Q. Are residents -- do residents</p>	<p>1 insufficient.</p> <p>2 Q. Have you analyzed the studies overall</p> <p>3 that show that the majority of complications do</p> <p>4 occur in the first 12 months?</p> <p>5 MR. CARTMELL: Object to the form. I</p> <p>6 think it misstates the evidence in the studies.</p> <p>7 A. Yeah. And it's also -- the</p> <p>8 complications they know of at that point. Because</p> <p>9 I can give you examples of bladder erosions that</p> <p>10 I've taken care of that I put in the sling that at</p> <p>11 7 years they're fine. At year 8 there's an</p> <p>12 erosion, which we've examined. So we have to look</p> <p>13 at the life of the patient.</p> <p>14 Q. BY MR. SNELL: In the studies that</p> <p>15 report on TVT retropubic at five years duration or</p> <p>16 more, what is the rate of mesh exposure occurring</p> <p>17 after five years.</p> <p>18 A. It's unknown.</p> <p>19 Q. You mentioned the Wang paper. Let me</p> <p>20 just make sure I have it here. I think I do.</p> <p>21 (Exhibit 19 marked.)</p> <p>22 Q. BY MR. SNELL: Is this the Wang paper</p> <p>23 you referenced, Doctor, with regard to TVT?</p> <p>24 A. Correct. 2004 publication, yes.</p> <p>25 Q. And that paper says on the first page</p>
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<p>1 typically have higher complication rates than the,</p> <p>2 you know, professors or the surgeons who teach</p> <p>3 them?</p> <p>4 A. It depends. If the resident is</p> <p>5 running solo and doing a case without any</p> <p>6 supervision, that possibly could be the case.</p> <p>7 However, if they have been well trained in a</p> <p>8 certain procedure and they're doing it solo and</p> <p>9 they've done more than anybody else -- they've</p> <p>10 done an acceptable number, their complications are</p> <p>11 going to be low. There's too many variables to be</p> <p>12 able to answer that question.</p> <p>13 Q. If a surgeon is a -- strike that.</p> <p>14 If a surgeon is more than an average</p> <p>15 surgeon, as you've stated, and he or she uses TVT</p> <p>16 retropubic device, based upon the data, you would</p> <p>17 agree then that the rate of complications are</p> <p>18 acceptable in his or her hands?</p> <p>19 A. Number one, acceptable, no. Number</p> <p>20 two, it depends upon what -- how much follow-up</p> <p>21 they have. And it's true, a surgeon can put in</p> <p>22 the device and at one year that woman has not</p> <p>23 experienced any complications yet. But that</p> <p>24 device is going to stay in her the rest of her</p> <p>25 life. That's why I'm saying all these studies are</p>	<p>1 "Prolene tape seems unusually biocompatible when</p> <p>2 used as a suburethral sling"; correct?</p> <p>3 It's all on the very first page.</p> <p>4 A. I'm sorry. Where are you?</p> <p>5 Q. Very first page. Right here.</p> <p>6 A. That's what it states, yes.</p> <p>7 Q. And so this paper by Wang is actually</p> <p>8 inconsistent with your belief that Prolene --</p> <p>9 strike that.</p> <p>10 Do you believe Prolene mesh is not</p> <p>11 biocompatible?</p> <p>12 A. I do not believe it is biocompatible,</p> <p>13 no.</p> <p>14 Q. In what percentage of patients is</p> <p>15 Prolene tape -- strike that.</p> <p>16 In what percentage of patients is the</p> <p>17 Prolene mesh used in TVT for the treatment of</p> <p>18 incontinence not biocompatible?</p> <p>19 A. That's impossible to know because</p> <p>20 there's been no good studies looking long-term at</p> <p>21 them.</p> <p>22 Q. Well, in this paper, out of 700 women</p> <p>23 that you reference, the rate of exposure was</p> <p>24 2.4 percent; correct?</p> <p>25 MR. CARTMELL: Object to the form.</p>

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<p>1 A. Correct. During the time period of</p> <p>2 this study, of 7 -- I don't see what the follow-up</p> <p>3 is.</p> <p>4 MR. CARTMELL: I think that misstates</p> <p>5 the evidence. The question assumes facts that are</p> <p>6 not in evidence.</p> <p>7 A. The paper, at least in the abstract,</p> <p>8 does not state the follow-up time. But this paper</p> <p>9 states defective vaginal healing that became</p> <p>10 clinically significant was 2.4 percent during the</p> <p>11 study period. But, again, I'm trying to find</p> <p>12 the -- this is at 1 to 3 months. Defective</p> <p>13 healing from 1 to 3 months, it looks like. So</p> <p>14 it's a very short-term study.</p> <p>15 Q BY MR. SNELL: Well, they actually</p> <p>16 looked at a longer time period than 3 months in</p> <p>17 this paper; right? It's just that the healing</p> <p>18 problems arose before three months; correct?</p> <p>19 A. The acute healing problems arose</p> <p>20 during that time, yes.</p> <p>21 Q. And so that means that 97.6 percent of</p> <p>22 the women did not have vaginal healing problems;</p> <p>23 right?</p> <p>24 A. At the time the study was conducted.</p> <p>25 Q. Fair enough.</p>	<p>1 complained of pain, 4 complained of dyspareunia, 5</p> <p>2 complained of vaginal bleeding and irritated</p> <p>3 voiding. And so to break it down into specific</p> <p>4 little complications is disingenuous at best. But</p> <p>5 going to that, yeah, 4 out of 700 complained</p> <p>6 specifically of dyspareunia during this short</p> <p>7 period of time, short period of follow-up.</p> <p>8 Q. And that's less than 1 percent; right?</p> <p>9 A. It's whatever the math is. Again, I</p> <p>10 don't -- I can trust you on the math, I think.</p> <p>11 Q. 5 out of 700's less than 1 percent;</p> <p>12 correct?</p> <p>13 MR. CARTMELL: He's answered you.</p> <p>14 Asked and answered.</p> <p>15 Q. BY MR. SNELL: I'm talking about the</p> <p>16 pain rate now. Not dyspareunia.</p> <p>17 A. Pain? Well, pain -- if you want pain,</p> <p>18 it's going to be different. So it's going to be</p> <p>19 9. Pain is roughly a 2 percent incidence of pain</p> <p>20 at that point in time.</p> <p>21 Q. Where do you get 2 percent?</p> <p>22 A. We have five women complained of pain.</p> <p>23 Four women complained of dyspareunia. Five women</p> <p>24 complained of vaginal bleeding and irritated</p> <p>25 voiding.</p>
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<p>1 And you see there were four women what</p> <p>2 complained of dyspareunia? I'm right here in the</p> <p>3 Results section.</p> <p>4 A. Five complained of pain and four</p> <p>5 complained of dyspareunia by themselves or their</p> <p>6 partner.</p> <p>7 Q. And so four women complained of</p> <p>8 dyspareunia by themselves or their partner or</p> <p>9 partner discomfort; right?</p> <p>10 A. Yes. So nine patients overall</p> <p>11 complained of pain.</p> <p>12 Q. All right.</p> <p>13 A. Four complained of dyspareunia.</p> <p>14 Q. And as for dyspareunia, that rate is</p> <p>15 0.57 percent; correct? This paper you point to.</p> <p>16 A. A -- well, it's 4 out of 700 patients</p> <p>17 at that short-term follow-up. That's how many</p> <p>18 complained of dyspareunia.</p> <p>19 Q. And does it sound about right that</p> <p>20 that rate is 0.57 percent.</p> <p>21 A. I would have to do the math on it.</p> <p>22 I'll have to take your word for that.</p> <p>23 Q. Well, 4 is certainly -- 4 women out of</p> <p>24 700 is certainly less than 1 percent; right?</p> <p>25 A. Well, if you look at this, 5 women</p>	<p>1 Q. Doesn't say those five complained of</p> <p>2 pain.</p> <p>3 A. No, they didn't. But they</p> <p>4 complained -- they complained of something else.</p> <p>5 So, again, what is always -- I'll let you have</p> <p>6 this, but as a doctor that takes care of patients</p> <p>7 who are crying in my office, you guys break down</p> <p>8 the complications. Yeah. So, yes. 9 patients in</p> <p>9 this series out of 700 complained of pain. The</p> <p>10 other ones weren't happy with vaginal bleeding,</p> <p>11 irritated voiding.</p> <p>12 Q. That was five who weren't happy with</p> <p>13 vaginal bleeding or irritated voiding; correct?</p> <p>14 A. Correct.</p> <p>15 Q. And they ended up, 7 patients in this</p> <p>16 series that you point to required excision of the</p> <p>17 exposed suburethral part of the sling; is that</p> <p>18 correct?</p> <p>19 A. That's correct.</p> <p>20 Q. So that was an excision rate of only</p> <p>21 1 percent in this entire cohort; right?</p> <p>22 A. During the very limited follow-up</p> <p>23 duration of this study, that is the number they</p> <p>24 came up with.</p> <p>25 Q. When you say limited follow-up</p>

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<p style="text-align: right;">Page 210</p> <p>1 duration, why do you say that?</p> <p>2 A. What's going to happen in 5 years? 10</p> <p>3 years? 20 years?</p> <p>4 Q. How about this? Why don't we look a</p> <p>5 little bit further below that. You see the mean</p> <p>6 follow-up of 68.2 months?</p> <p>7 A. Okay. What about 69 months -- I'm</p> <p>8 sorry.</p> <p>9 Q. That's over five years, isn't it,</p> <p>10 Doctor?</p> <p>11 A. And as I have mentioned over and over</p> <p>12 and over, this is an implantable medical device,</p> <p>13 as you mentioned. There are studies out there.</p> <p>14 Klinge, 15 years, degradation continues. This is</p> <p>15 a progressive process. I see these patients in my</p> <p>16 clinic that aren't being followed by anybody. So</p> <p>17 I'm saying 5 years, that's a step in the right</p> <p>18 direction. But if a woman lives 30 years beyond</p> <p>19 that, what's going to happen in that time frame?</p> <p>20 Our data suggests it's going to get worse.</p> <p>21 MR. SNELL: Move to strike.</p> <p>22 Q. BY MR. SNELL: In this paper you point</p> <p>23 to -- you pointed me to, at over 5 years</p> <p>24 follow-up, there was only 1 percent rate of mesh</p> <p>25 excision to treat the exposure; right?</p>	<p style="text-align: right;">Page 212</p> <p>1 MR. SNELL: You're not testifying,</p> <p>2 Tom, please.</p> <p>3 MR. CARTMELL: -- there's 7 erosions</p> <p>4 when there's 17 erosions. In fairness.</p> <p>5 MR. SNELL: You know what. You're</p> <p>6 totally off base.</p> <p>7 MR. CARTMELL: I am?</p> <p>8 MR. SNELL: Yes.</p> <p>9 MR. CARTMELL: Tell me how.</p> <p>10 MR. SNELL: On your time I was asking</p> <p>11 him about erosions that needed surgical -- where's</p> <p>12 the paper? We just went through this, didn't we,</p> <p>13 Doctor.</p> <p>14 MR. CARTMELL: 17 erosions. 17</p> <p>15 erosions, it says right here.</p> <p>16 MR. SNELL: Tom, you're being</p> <p>17 nonsensical. I asked him about the ones that</p> <p>18 required excision.</p> <p>19 MR. CARTMELL: No, you didn't. You</p> <p>20 said erosions in general, and the record will</p> <p>21 reflect that.</p> <p>22 Q. BY MR. SNELL: Sir, don't you remember</p> <p>23 me asking you about 7 of those patients required</p> <p>24 excision of the exposed suburethral part of the</p> <p>25 sling? Didn't I ask you about that?</p>
<p style="text-align: right;">Page 211</p> <p>1 A. That is what the study stated at five</p> <p>2 years, yes.</p> <p>3 Q. So that means at a mean follow-up</p> <p>4 greater than 5 years, 99 percent of the women in</p> <p>5 this entire large cohort didn't need a mesh</p> <p>6 excision procedure; correct?</p> <p>7 A. The key is yet.</p> <p>8 Q. And there are other studies that</p> <p>9 report --</p> <p>10 MR. CARTMELL: Just for the record, I</p> <p>11 want it to be clear, because I think it's unfair</p> <p>12 to the witness that you've been representing that</p> <p>13 there was a small number of erosions. And I think</p> <p>14 there were 17 erosions in the cohort. And I want</p> <p>15 the record to be clear for that.</p> <p>16 MR. SNELL: I think -- the study says</p> <p>17 what it says, so I can't --</p> <p>18 MR. CARTMELL: Yeah, but you're just</p> <p>19 kind of trying to trick him, you know, because</p> <p>20 you --</p> <p>21 MR. SNELL: I'm not tricking him. He</p> <p>22 pointed to this study, Tom. He knows this study.</p> <p>23 Don't try to tell me I'm tricking a witness about</p> <p>24 a paper he told me -- he's pointing me to.</p> <p>25 MR. CARTMELL: So don't say --</p>	<p style="text-align: right;">Page 213</p> <p>1 A. You asked me a question. I can't</p> <p>2 remember the specific details of it.</p> <p>3 Q. BY MR. SNELL: But it says seven</p> <p>4 required excision of the exposed suburethral part</p> <p>5 of the sling; right?</p> <p>6 A. That's what that says there, and the</p> <p>7 other part says 17 out of 100 had defective</p> <p>8 vaginal healing.</p> <p>9 Q. And it gives the measurement, CA 1</p> <p>10 times 0.5 centimeters; correct?</p> <p>11 MR. CARTMELL: Okay. Now, it's all on</p> <p>12 the record. Now it's fair.</p> <p>13 MR. SNELL: It was fair before. He</p> <p>14 cited to the document. He knows the study.</p> <p>15 (Exhibit 20 marked.)</p> <p>16 Q. BY MR. SNELL: Giving you one of the</p> <p>17 publications by Klinge, Alloplastic Implants for</p> <p>18 the Treatment of Stress Urinary Incontinence and</p> <p>19 Pelvic Organ Prolapse.</p> <p>20 You see this?</p> <p>21 A. Yes, I do.</p> <p>22 Q. Whereas you cited to Klinge about</p> <p>23 hernia and other papers, you didn't cite to his</p> <p>24 discussion of the TVT mesh; did you?</p> <p>25 A. I don't recall that specifically.</p>

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<p style="text-align: right;">Page 214</p> <p>1 Q. Look for where Klinge was writing 2 about meshes in stress urinary incontinence. 3 You there? 4 A. Yes. I mean, I'm sorry. I'm at the 5 Meshes and Stress Urinary Incontinence. I'm there 6 now. 7 Q. All right. And you saw Dr. Klinge was 8 one of the authors of this section; right? 9 A. Correct. 10 Q. And it says, "At present the gold 11 standard in SUI surgery is the suburethral sling 12 using either the tension-free vaginal tape (TVT) 13 or the transobturator tape (TOT) technique"; 14 correct? 15 A. That's what he states, yes. 16 Q. And do you disagree with Dr. Klinge? 17 A. I disagree. 18 Q. It said, the initial concern that the 19 meshes used might lead to high rates of erosions, 20 did not hold true when macroporous polypropylene 21 was used; correct? 22 A. That's what it states, yes. 23 Q. And here when Dr. Klinge is talking 24 about macroporous polypropylene in the context of 25 stress urinary incontinence, he's talking about</p>	<p style="text-align: right;">Page 216</p> <p>1 referencing to the Meschia study. 2 Q. And you know that that's a study that 3 looks at the Ethicon TVT retropubic device? 4 A. I'd have to look back at the study. I 5 don't remember the study. 6 Q. Okay. So at least in the context of 7 the intended use to treat stress urinary 8 incontinence with regard to the TVT device, he 9 reports that tape is a type 1 macroporous tape? 10 A. That's what he reports in 2010. 11 Q. Right. 12 A. Which then reflects data from 2008. 13 And that's what he states. 14 I disagree with it. Be interesting to 15 what he says now. 16 Q. Now that he's been paid hundreds of 17 thousands of dollars by the plaintiffs' lawyers in 18 the mesh litigation? 19 MR. CARTMELL: Object to the form. 20 It's argumentative. Be distracting. 21 A. If you want to go on the record that 22 he's being biased. 23 Q BY MR. SNELL: Do you know how many 24 royalties he -- Dr. Klinge received on Vypro? 25 A. I'm not familiar with that number</p>
<p style="text-align: right;">Page 215</p> <p>1 the mesh in TVT; correct? 2 MR. CARTMELL: Object to the form. 3 A. No. He doesn't state which he's 4 talking -- referring to. The sentence prior, it 5 says TVT or transobturator tape. There's a lot of 6 different ones out there. And then he says, "The 7 initial concern that meshes." He does not say 8 TVT. So all he's saying is meshes. 9 Q BY MR. SNELL: Well, you see below 10 that, right, where he talks about -- he follows up 11 on his point. 12 He says, "There was a zero percent 13 exposure rate using the classical TVT (Type 1 14 macroporous monofilament polypropylene) mesh in 15 the same trial"; correct? 16 A. Well, that's in the second -- in the 17 next paragraph down. I'm talking about the 18 sentence you showed me. Initial concern that 19 meshes. So it doesn't say TVT. We can agree it 20 says meshes, and I'll agree that's what it states, 21 but he doesn't say TVT. 22 Q. We can agree that he says the 23 classical TVT (type 1 macroporous monofilament 24 polypropylene) mesh; right? 25 A. That's what he's saying when he's</p>	<p style="text-align: right;">Page 217</p> <p>1 because I'm doing involvement of TVT case, not 2 Vypro. 3 Q. Do you know how many royalties 4 Dr. Klinge has received for ULTRAPRO? 5 A. The same answer as before, because I 6 know what data I've been provided on TVT. I have 7 not been provided confidential data on Vypro or 8 the other ones. 9 Q. And you don't disagree that when Amid 10 type 3 mesh, used for intravaginal slingplasty, 11 the vaginal erosion rate was 9 percent, and the 12 rate was 0 percent with TVT? 13 MR. CARTMELL: Object to the form. 14 A. I agree with the first part. I don't 15 agree with the second part. 16 The Amid type 3 like the ObTape, which 17 I'm very familiar with, had an unacceptably 18 significant complication rate with it. 19 Q BY MR. SNELL: And you didn't cite to 20 this writing by Klinge in your expert report; did 21 you? 22 A. I cited Klinge multiple times. I 23 don't know if this specific -- this is a book 24 chapter. I quoted this one. Book chapters I tend 25 not to quote.</p>

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<p style="text-align: right;">Page 218</p> <p>1 Q. Well, this is one place in the medical 2 literature where Dr. Klinge discussed his views on 3 what type of mesh TVT mesh was in the application 4 of treating stress urinary incontinence and 5 whether or not it was the gold standard. 6 Have you seen that published anywhere 7 else? 8 MR. CARTMELL: Objection. 9 Q BY MR. SNELL: By Dr. Klinge. 10 MR. CARTMELL: Objection. And move to 11 strike this statement of counsel. 12 A. And I agree with you completely, and 13 that should tell you something about Klinge's 14 expertise, as far as a stress urinary incontinence 15 surgeon, which he is not. He's a mesh expert. 16 But he's not a transvaginal surgeon. He's never 17 been involved in one of these cases. So you 18 search around and find one reference where he's 19 quoting something in the book, okay, that's what 20 it is. 21 Q BY MR. SNELL: He doesn't just quote 22 something in a book. He's actually citing data, 23 randomized trial data on TVT versus an alternative 24 mesh; doesn't he? 25 A. I'm saying he is not a surgeon. He's</p>	<p style="text-align: right;">Page 220</p> <p>1 know? 2 MR. SNELL: So the question is would 3 you -- well, I take it he's read Dr. Klinge's 4 writings. He's seen Dr. Klinge's statements. 5 MR. CARTMELL: What writings are you 6 asking him about? If you have writings about 7 DynaMesh that you want to ask him about, put them 8 in front of him. Why all the questions about 9 studies and things that you don't even let him 10 look at. 11 MR. SNELL: He can look at anything he 12 wants. 13 MR. CARTMELL: Then put it in front of 14 him. 15 MR. SNELL: It's not my job to put it 16 in front of him. It's the job of your witness to 17 bring his file. Secondly, he cites to Klinge 18 about 100 times in the report, and not once does 19 he acknowledge any of this. 20 MR. CARTMELL: If you're going to ask 21 him about a study specifically on it that's on his 22 reliance list, then bring it with you and ask him 23 questions and let him look at it so it can be 24 fair. How about that? How about that? 25 MR. SNELL: He could bring his own</p>
<p style="text-align: right;">Page 219</p> <p>1 not providing expertise as a pelvic surgeon like I 2 am. He's a mesh expert, a very good one, but he 3 is not a pelvic surgeon. 4 Q. Do you know how many royalties 5 Dr. Klinge gets with regard to his work with the 6 German DynaMesh mesh? 7 A. I have not heard a number, no. 8 Q. You know he does get money from that 9 mesh; right? 10 A. I just said I don't know. I don't 11 know. I'm not a faithful apostle of Dr. Klinge. 12 I don't know what he does. 13 Q. Do you acknowledge he's got a 14 conflict -- 15 MR. CARTMELL: All you got to do is 16 answer do you know or not. 17 A. I do not know. 18 Q BY MR. SNELL: You know that he has a 19 conflict of interest when it comes to DynaMesh; 20 don't you? 21 MR. CARTMELL: What it comes to what? 22 MR. SNELL: DynaMesh, D-y-n-a-M-e-s-h. 23 It's a mesh that's not even available here in the 24 United States. 25 MR. CARTMELL: So then why would he</p>	<p style="text-align: right;">Page 221</p> <p>1 file. How about that? That was asked and 2 requested of him, Tom. 3 MR. CARTMELL: You have everything he 4 has reviewed. 5 MR. SNELL: Tom, my experts bring 6 their file to the depositions. 7 MR. CARTMELL: Wrong. 8 MR. SNELL: You remember when you 9 deposed Denise Selzer she showed up with nine 10 boxes of stuff. 11 MR. CARTMELL: Denise Selzer did. 12 MR. SNELL: Christina Pramudji showed 13 up with boxes and boxes and boxes of stuff. 14 MR. CARTMELL: Not when I deposed her. 15 MR. SNELL: Get for real. You know 16 she did. Crazy. 17 A. But to address your question, as far 18 as conflict of interest, if he truly does have 19 conflict of interest and bias, then based upon 20 this here he's coming out in support of TVT. So I 21 see a fault in your logic. 22 Q BY MR. SNELL: I don't have a logic. 23 I'm asking you a question. 24 A. Well, I know you don't have a logic 25 and that's what I've been pointing out.</p>

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<p style="text-align: right;">Page 222</p> <p>1 Q. My question is: You were aware of 2 these writings by Klinge with regard to TVT and 3 that mesh and the specific intended use of stress 4 urinary incontinence before you wrote your report; 5 right? 6 A. I'm aware of this reference. 7 Q. Yes. You were -- 8 A. The one that I'm holding, Exhibit 20. 9 I don't recall if I've ever been aware of this. 10 Q. The plaintiffs' lawyers never gave 11 that to you? 12 A. I don't recall if they have. I have 13 thousands of pages they've sent me. It may have 14 been in there somewhere. I have not seen this. 15 Again, if he were a pelvic surgeon, I would be 16 putting weight into his comments on gold standard 17 and things. But all he's doing is parroting what 18 he's read somewhere else. So, again, it is what 19 it is. 20 Q. Can you point me to any other 21 publications by Klinge where he assesses the TVT 22 retropubic device in the application of stress 23 incontinence and discusses the clinical studies on 24 that device like he did in that paper I just 25 showed you, Exhibit 20?</p>	<p style="text-align: right;">Page 224</p> <p>1 So, again, I'm agreeing with you and disagreeing 2 with you at the same time. Not to be difficult. 3 MR. SNELL: Okay. Let's take a quick 4 break so I can get organized. 5 (Recessed from 3:05 p.m. to 6 3:07 p.m.) 7 Q BY MR. SNELL: I want to ask you about 8 your opinions about the mechanical cut of the TVT 9 retropubic device. 10 You've mechanically cut mesh before? 11 A. Just the sacrocolpopexy mesh. Not 12 sling mesh. 13 Q. And did it ever concern you when you 14 were cutting sacrocolpopexy mesh mechanically? 15 A. It didn't. And now it does. 16 Q. Do you still cut sacrocolpopexy mesh? 17 A. No. We modified -- well, we're in the 18 process of modifying it to using Restoril, which 19 will not hopefully have that problem. It's 20 already hemmed. And that is a concern of mine 21 which I now counsel my patients on. 22 Q. And is it fair to say that you believe 23 the laser cut TVT mesh is defective? 24 A. I think it's treated one -- to 25 specifically answer your question, yes.</p>
<p style="text-align: right;">Page 223</p> <p>1 MR. CARTMELL: Object to the form. It 2 misstates the actual paper. 3 A. He has studied extensively hernia 4 meshes. TVT is a hernia mesh. But to put all the 5 dots together as you very narrowed it down to, the 6 answer to that is no, not that I am aware of. 7 Q BY MR. SNELL: My focus is the 8 intended application of the treatment of stress 9 incontinence and those studies alone. 10 You haven't seen that paper or those 11 papers? 12 A. As you word it there, I have not seen 13 that. The intended application of the TVT mesh 14 was actually for hernias. Not for female stress 15 incontinence. So, again, he has studied the 16 intended purpose of that mesh. He has not studied 17 it when it's been put into the vagina. 18 Q. For the TVT device, that's what I'm 19 referring to for its intended -- you've 20 acknowledged that the TVT retropubic device is 21 intended to treat stress urinary incontinence; 22 right? 23 A. The device is, but the mesh intended 24 use was for hernias, which was then extended to 25 the application of stress urinary incontinence.</p>	<p style="text-align: right;">Page 225</p> <p>1 Q. I didn't see in your expert report 2 where you cite to any TVT studies with regard to 3 clinical complications occurring at a 4 statistically higher rate with mechanical cut TVT 5 mesh as compared to laser cut TVT mesh. 6 Is that a fair summary of your report? 7 A. You are correct. I have not heard of 8 a study with that. However, I'm basing that on 9 Nilsson's comment of a four-time -- four times 10 increased risk of vaginal extrusion with a laser 11 cut. 12 Q. What comment is this by Nilsson? I'm 13 sorry. 14 A. That was in one of the documents I 15 read. I don't know where I read it, but it's in 16 the document. 17 Q. What methodology did you use to select 18 that one quote by Nilsson? 19 A. Because he is arguably one of the 20 world's experts on it. And so I value his opinion 21 on this. 22 Q. Do you also value his statement in the 23 company documents that he will not use laser cut 24 mesh; that he only uses mechanical cut mesh? 25 A. Absolutely. That's supporting what I</p>

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<p style="text-align: right;">Page 226</p> <p>1 just said.</p> <p>2 Q. So you're aware that Nilsson only --</p> <p>3 in the company documents, reports that he will</p> <p>4 only use mechanical cut mesh?</p> <p>5 A. That's -- I don't know what his recent</p> <p>6 statements are, but that the document that I read,</p> <p>7 which that source can be found, he said he would</p> <p>8 not use the laser cut because of the four times</p> <p>9 increased risk of vaginal extrusion, and he would</p> <p>10 only use the mechanical. Then I read the other</p> <p>11 individuals stating the exact opposite. So I get</p> <p>12 conflicting evidence. I have not seen, to the</p> <p>13 best of my knowledge and it may be out there</p> <p>14 somewhere, a study, comparative, randomized</p> <p>15 clinical study of the two. I've not seen it.</p> <p>16 Q. Are you aware of any TVT retropubic</p> <p>17 clinical data that reports that there's a higher</p> <p>18 rate of complications with mechanically cut mesh</p> <p>19 compared to laser cut mesh?</p> <p>20 A. I don't think overall there's going to</p> <p>21 be a higher risk from one or the other. They're</p> <p>22 both bad and both have their set of complications.</p> <p>23 So you're trading one set of problems for another</p> <p>24 set of problems.</p> <p>25 Q. What studies are you specifically</p>	<p style="text-align: right;">Page 228</p> <p>1 ever read on TVT. If you have something</p> <p>2 different, then I'll keep an open mind. I have</p> <p>3 yet to see any paper describe we're using</p> <p>4 mechanically cut or we're using laser cut. So I</p> <p>5 can't base it upon that.</p> <p>6 Q. Okay. So when I was asking about what</p> <p>7 papers you were talking about, I thought you were</p> <p>8 talking about Ethicon company documents and not</p> <p>9 medical literature.</p> <p>10 A. No. That was one of them. The</p> <p>11 internal documentation -- I'll just be clear.</p> <p>12 As I stated in the previous answer,</p> <p>13 internal Ethicon documentations, medical</p> <p>14 literature, the emails back and forth, and then my</p> <p>15 clinical experience. That's how I came by it.</p> <p>16 I am not here today to say that laser</p> <p>17 cut is better or worse. They're both bad in my</p> <p>18 opinion.</p> <p>19 Q. So with regard to your selection of</p> <p>20 which company documents to put in your expert</p> <p>21 report on this mechanical cut issue, what was your</p> <p>22 methodology in selecting those particular company</p> <p>23 documents?</p> <p>24 A. My methodology of what I reviewed is</p> <p>25 very simple. Every document that I was provided</p>
<p style="text-align: right;">Page 227</p> <p>1 relying upon for your opinion with regard to the</p> <p>2 mechanical cut TVT retropubic mesh, if any?</p> <p>3 A. Well, that's what I'm talking about.</p> <p>4 The methodology that I have used with this,</p> <p>5 concerning specifically mechanically cut, is</p> <p>6 obviously the internal documentation, with</p> <p>7 complaints coming in about the fraying, roping,</p> <p>8 particle loss, the inflammation. Reviewing of the</p> <p>9 papers talking about various different</p> <p>10 complications. My clinical experience dealing</p> <p>11 with patients. Last week alone, there's one</p> <p>12 patient. Week before that, three, which were all</p> <p>13 TVT patients. Where that I see this mechanically</p> <p>14 cut mesh. Then my discussion with colleagues at</p> <p>15 international and national meetings. So all that</p> <p>16 is going into it.</p> <p>17 Q. You said the papers. You reference</p> <p>18 papers. Are you talking about Ethicon documents?</p> <p>19 A. Correct. Well, I mean the medical</p> <p>20 literature, too.</p> <p>21 Q. That's what I'm asking. What medical</p> <p>22 literature on TVT reports complications</p> <p>23 attributed -- attributed to the mechanical cut</p> <p>24 nature of the mesh?</p> <p>25 A. The defect in -- and every paper I've</p>	<p style="text-align: right;">Page 229</p> <p>1 with internal documentation from Ethicon I</p> <p>2 reviewed.</p> <p>3 Q. So you were provided those by the</p> <p>4 plaintiffs' lawyers?</p> <p>5 A. Correct.</p> <p>6 Q. My question to you is this: Let's</p> <p>7 focus on your methodology for which ones you</p> <p>8 decided to cite in your expert report as support</p> <p>9 for your points.</p> <p>10 What was the methodology in that?</p> <p>11 A. You have to -- you have to analyze --</p> <p>12 MR. CARTMELL: Well, just for</p> <p>13 clarification, you mean because they're all cited</p> <p>14 in his report.</p> <p>15 MR. SNELL: No, they're not.</p> <p>16 MR. CARTMELL: There's a reliance</p> <p>17 list.</p> <p>18 MR. SNELL: There's a reliance list,</p> <p>19 but he cited certain things.</p> <p>20 MR. CARTMELL: Okay. So you're</p> <p>21 distinguishing between what's in a footnote versus</p> <p>22 what's in the reliance list that's attached.</p> <p>23 MR. SNELL: Of course, because, I'm</p> <p>24 sure, everything in the reliance list doesn't</p> <p>25 support the things he says.</p>

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<p>1 MR. CARTMELL: Well, everything on his</p> <p>2 reliance list is information he used in forming</p> <p>3 his opinions and relies on.</p> <p>4 MR. SNELL: You're speaking -- you're</p> <p>5 doing a speaking objection.</p> <p>6 MR. CARTMELL: Well, I'm responding to</p> <p>7 your statement you just made. You're talking</p> <p>8 about only the citations in the report.</p> <p>9 MR. SNELL: Yes. That is my question.</p> <p>10 That is my question. Do I need to repose it again</p> <p>11 so we have a clear record?</p> <p>12 THE DEPONENT: No.</p> <p>13 Q BY MR. SNELL: Why don't we just do it</p> <p>14 again.</p> <p>15 A. That's fine.</p> <p>16 Q. Otherwise there's just going to be</p> <p>17 four pages of gap.</p> <p>18 What specific methodology, did you use</p> <p>19 in determining what Ethicon documents you would</p> <p>20 cite to in support of your opinions where you</p> <p>21 listed them in the footnotes?</p> <p>22 A. Okay. I have to look at the body of</p> <p>23 knowledge out there on medical literature, my</p> <p>24 clinical experience and what I see day to day,</p> <p>25 correlating that with what was known and discussed</p>	<p>1 be your methodology for excluding it or not</p> <p>2 referencing it in your report?</p> <p>3 MR. CARTMELL: It was on his reliance</p> <p>4 list.</p> <p>5 A. Yeah. To a certain extent, surgeon</p> <p>6 preference is important, and then also not</p> <p>7 important. So certain surgeons choose to do one</p> <p>8 product over the another. The fact that</p> <p>9 51 percent like the mechanical cut and 49 don't,</p> <p>10 it doesn't matter to me. Again, we're not talking</p> <p>11 about one product being great and the other one</p> <p>12 being horrible. They're both bad. So to me it's</p> <p>13 immaterial.</p> <p>14 Q BY MR. SNELL: Did you assess or look</p> <p>15 at the reported rates of sales of mechanical cut</p> <p>16 versus laser cut in the United States?</p> <p>17 A. Well, from my angle as a doctor, the</p> <p>18 needs of the patient come first. And sales are</p> <p>19 not an issue that I'm going to be concerned about.</p> <p>20 Q. So the answer is, no, you didn't look</p> <p>21 at that?</p> <p>22 A. The answer is what I just stated.</p> <p>23 Q. Sir, my question is very simple, which</p> <p>24 is: Did you look at it?</p> <p>25 I understand you want to give me a</p>
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<p>1 in the Ethicon documents, whether it be from their</p> <p>2 scientists, from their medical experts, from their</p> <p>3 clinicians calling in, correlating that and does</p> <p>4 it all fit. Everything has to fit logically,</p> <p>5 okay, and that was what was included in this.</p> <p>6 Q. So, for example, did you see company</p> <p>7 documents that indicated that the majority of</p> <p>8 surgeons in the United States actually prefer</p> <p>9 mechanical cut mesh as opposed to laser cut?</p> <p>10 A. I've seen that, yes. Well, I'm sorry.</p> <p>11 Let me take that -- strike that.</p> <p>12 I do remember seeing and reading that</p> <p>13 certain physicians would not change to the laser</p> <p>14 cut. I can't say that the majority did. I also</p> <p>15 see that certain surgeons would not use the</p> <p>16 mechanical one because of the fraying and the</p> <p>17 particle loss. So I don't know the percentage of</p> <p>18 who uses what.</p> <p>19 Q. So you were not provided documents</p> <p>20 that state that the majority of surgeons in the</p> <p>21 United States who use TVT prefer the mechanical</p> <p>22 cut mesh as opposed to laser cut; fair?</p> <p>23 A. I may have been provided that. I</p> <p>24 don't recall that specific document.</p> <p>25 Q. If that document existed, what would</p>	<p>1 speech on things, but if you could just give me a</p> <p>2 yes or no answer, then I can move on. If you say</p> <p>3 no, then I'm going to move on.</p> <p>4 A. Well, no, because my speech, as you</p> <p>5 did, is based upon my taking care of patients who</p> <p>6 are crying in my office from pain. So I don't</p> <p>7 dismiss it as a speech. But medical marketing</p> <p>8 sales are not something that's going to factor</p> <p>9 into my decision.</p> <p>10 Q. I believe earlier you were talking</p> <p>11 about complications, and I think it may have been</p> <p>12 around mesh exposures, where you said there would</p> <p>13 be numerous different factors like patient</p> <p>14 factors, surgeon factors, the mesh.</p> <p>15 Do you recall that?</p> <p>16 A. Yeah. Concerning vaginal exposure. I</p> <p>17 don't recall if I mentioned patient factors</p> <p>18 involved in it, but, I mean, maybe I did. I</p> <p>19 don't -- I'd have to see exactly what I said.</p> <p>20 Q. I wrote it down.</p> <p>21 A. It's a multifactorial problem that</p> <p>22 leads to that complication.</p> <p>23 Q. What are the patient factors involved?</p> <p>24 A. Well, that's difficult because it's --</p> <p>25 I don't know of anyone ever studying to show</p>

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<p>1 consistently a patient factor being involved in</p> <p>2 the exposures. Smoking, I'm not aware of.</p> <p>3 Obesity, I'm unaware of. Vaginal atrophy -- I</p> <p>4 don't know of patient factors that can be</p> <p>5 consistently proven to be a factor in vaginal</p> <p>6 exposure.</p> <p>7 Q. You are -- vaginal atrophy is a</p> <p>8 condition that women have that can progress or get</p> <p>9 worse as they get older in their postmenopausal</p> <p>10 years if not supplemented with some type of</p> <p>11 estrogen; fair?</p> <p>12 A. There's the possibility of that, yes.</p> <p>13 Not in all cases.</p> <p>14 Q. But is that a common finding in women</p> <p>15 who are postmenopausal that there is some degree</p> <p>16 of vaginal atrophy?</p> <p>17 A. It's not uncommon, let's put it that</p> <p>18 way. So, yeah, it does occur.</p> <p>19 Q. Is there a recognized weight</p> <p>20 classification specific to stress urinary</p> <p>21 incontinence slings that has been endorsed and put</p> <p>22 out by any of the pertinent professional medical</p> <p>23 societies?</p> <p>24 A. Pertaining to what? I guess I don't</p> <p>25 understand your question. That they should or</p>	<p>1 standard thing that's out there. Same thing goes</p> <p>2 for pore size, too.</p> <p>3 Q. And my focus is on the intended use</p> <p>4 with the stress incontinence device and the</p> <p>5 application to treat stress incontinence.</p> <p>6 A. Closest thing I think would have to be</p> <p>7 a Clave study, breaking it down to the various</p> <p>8 weights, I think, if I'm answering your question</p> <p>9 correctly. But that's not as it pertains</p> <p>10 specifically to SUI.</p> <p>11 Q. Right. That's what I'm looking for is</p> <p>12 SUI.</p> <p>13 A. I am not aware of that specific narrow</p> <p>14 application.</p> <p>15 Q. For SUI, the slings are typically</p> <p>16 around 1 centimeter wide.</p> <p>17 A. 1 to 1.5, probably.</p> <p>18 Q. Ethicon's TVT is reported to be about</p> <p>19 1.1 centimeters; correct?</p> <p>20 A. As it comes out of the box, which is</p> <p>21 an important distinction.</p> <p>22 Q. Yeah.</p> <p>23 A. But, yeah, they're all about that</p> <p>24 width.</p> <p>25 Q. Is it a fair statement that all of the</p>
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<p>1 should not get a TVT?</p> <p>2 Q. No, no. For the intended use of</p> <p>3 stress urinary incontinence.</p> <p>4 Is there a recognized weight</p> <p>5 classification system for slings?</p> <p>6 A. Well, no. The BMI is the standard</p> <p>7 what is used. And but there's not, as it pertains</p> <p>8 specifically to SUI treatments.</p> <p>9 Q. I think you and I -- we weren't on the</p> <p>10 same wavelength.</p> <p>11 For the weight of the mesh --</p> <p>12 A. Oh, okay.</p> <p>13 Q. -- and the intended use of treating</p> <p>14 stress urinary incontinence, is there a recognized</p> <p>15 weight classification system that's endorsed by</p> <p>16 the professional societies?</p> <p>17 A. No. As far as -- even in industry,</p> <p>18 industry and surgical societies, there is -- as</p> <p>19 far as I know, there is no specific</p> <p>20 classification. I think they have heavy weight --</p> <p>21 you know, Cobb and others taught about heavy</p> <p>22 weight. So there would be that. And above</p> <p>23 certain -- or below certain numbers would become</p> <p>24 medium weight and lightweight. I don't know if I</p> <p>25 can -- I can't quote a society that has this</p>	<p>1 mesh slings, synthetic mesh slings that are used</p> <p>2 to treat stress urinary incontinence have a weight</p> <p>3 of more than 60 grams per meter squared?</p> <p>4 MR. CARTMELL: Object to the form.</p> <p>5 May call for speculation.</p> <p>6 Answer if you know.</p> <p>7 A. Yeah. All I can speak to is Aris,</p> <p>8 which I know is at 70. TVT at 105. I don't know</p> <p>9 that the other products.</p> <p>10 Q. BY MR. SNELL: You read Moalli's paper</p> <p>11 on the biomechanical evaluation of slings?</p> <p>12 A. I read it at one point in time. Not</p> <p>13 recently.</p> <p>14 Q. It has a table in there where it has</p> <p>15 the reported weights of the different slings.</p> <p>16 A. Okay.</p> <p>17 Q. Is that a paper you're relying on, the</p> <p>18 Moalli paper?</p> <p>19 A. That's in my reliance list. But I'm</p> <p>20 just saying I haven't read it recently. You're</p> <p>21 referring to the 2007 paper?</p> <p>22 Q. Give me the title and I'll tell you.</p> <p>23 A. Tensile Properties of Five Commonly</p> <p>24 Used Mid-Urethral Slings Relative to the TVT, by</p> <p>25 Moalli, et al., June of 2007. Published in 2008.</p>

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<p style="text-align: right;">Page 238</p> <p>1 Excuse me.</p> <p>2 Q. That's it. Yeah. Is that a paper</p> <p>3 you're relying on?</p> <p>4 A. Yes.</p> <p>5 Q. Are there any studies in the stress</p> <p>6 incontinence application with the use of TVT that</p> <p>7 show that a lighter weight mesh is either more</p> <p>8 efficacious -- strike that.</p> <p>9 Let me just say is more efficacious</p> <p>10 than the TVT?</p> <p>11 A. Can you rephrase the question, because</p> <p>12 as I'm reading it. I can't quite understand.</p> <p>13 Q. Absolutely. Yeah.</p> <p>14 Are there any clinical studies</p> <p>15 evaluating efficacy in women with stress urinary</p> <p>16 incontinence that show that a lighter weight mesh</p> <p>17 works better than the TVT retropubic device?</p> <p>18 MR. CARTMELL: Object to the form.</p> <p>19 A. No, I don't think the weight of the</p> <p>20 mesh --</p> <p>21 MR. CARTMELL: Can I -- can I get</p> <p>22 this? Can we take a break.</p> <p>23 MR. SNELL: Yeah. An opportune time.</p> <p>24 (Recessed from 3:31 p.m. to</p> <p>25 3:32 p.m.)</p>	<p style="text-align: right;">Page 240</p> <p>1 of treating stress urinary incontinence?</p> <p>2 A. No. I've only seen it in pelvic organ</p> <p>3 prolapse data and in meshes. Meshes for hernia</p> <p>4 repairs, but it was not extrapolated, even though</p> <p>5 Ethicon knew about it, into stress urinary</p> <p>6 incontinence.</p> <p>7 Q. All right. And you're not testifying</p> <p>8 that a lighter weight mesh would have worked</p> <p>9 better than the TVT mesh in the TVT retropubic</p> <p>10 application to treat stress urinary incontinence;</p> <p>11 are you?</p> <p>12 MR. CARTMELL: Are you talking about</p> <p>13 efficacy only?</p> <p>14 MR. SNELL: I can go with efficacy</p> <p>15 first.</p> <p>16 A. There is no data out there on it.</p> <p>17 That would be an important thing to do before a</p> <p>18 launch is to study that to determine efficacy</p> <p>19 prior to widespread use.</p> <p>20 Q BY MR. SNELL: You would agree it's a</p> <p>21 benefit for the TVT retropubic device that they do</p> <p>22 have studies of 5 years, 10 years, or more</p> <p>23 duration in the literature?</p> <p>24 MR. CARTMELL: Object to the form.</p> <p>25 A. Yes, as we mentioned concerning</p>
<p style="text-align: right;">Page 239</p> <p>1 MR. SNELL: Can you read back the</p> <p>2 question?</p> <p>3 (The reporter read the record as</p> <p>4 requested.)</p> <p>5 A. As is worded there, I'm not aware of</p> <p>6 it. I mean, Cobb and internal Ethicon documents</p> <p>7 talk about lighter weight being better, fewer</p> <p>8 complications, sort of things. But as you</p> <p>9 specifically narrow it down to TVT, there is not</p> <p>10 that study.</p> <p>11 Q BY MR. SNELL: And my question -- the</p> <p>12 initial question was on efficacy.</p> <p>13 A. No. As far as I know.</p> <p>14 Q. Okay.</p> <p>15 A. There is nothing out there, as far as</p> <p>16 the lightweights.</p> <p>17 The move was in hernias and pelvic</p> <p>18 organ prolapse to go to lighter weight because of</p> <p>19 the complications, but that was decided against</p> <p>20 with TVT.</p> <p>21 Q. And so my question is I want to get</p> <p>22 into -- ask you about the complications.</p> <p>23 Are you aware of any clinical studies</p> <p>24 showing a lower rate of complications in women who</p> <p>25 receive a lighter weight mesh for the intended use</p>	<p style="text-align: right;">Page 241</p> <p>1 efficacy, but not safety.</p> <p>2 Q BY MR. SNELL: Well, there's --</p> <p>3 A. The lighter meshes, the larger pore,</p> <p>4 lighter weight meshes are for complications. Not</p> <p>5 for efficacy.</p> <p>6 Q. And I understand you say that with</p> <p>7 regard to prolapse and hernia. My question to you</p> <p>8 is: With regard to complications, is it your</p> <p>9 opinion that a lighter weight mesh was used in the</p> <p>10 application of TVT for the treatment of stress</p> <p>11 incontinence, cut to 1.1 centimeters, that there</p> <p>12 would be a lower complication rate?</p> <p>13 A. There's the theoretical possibility of</p> <p>14 that. However, my ultimate opinion is no meshes</p> <p>15 should be placed transvaginally.</p> <p>16 Q. Fair enough.</p> <p>17 You mentioned the Clave study. That</p> <p>18 was not a study that reported on the use of the</p> <p>19 TVT retropubic device in women who had been</p> <p>20 treated for stress urinary incontinence; correct?</p> <p>21 A. Correct. That was, as I recall, for</p> <p>22 pelvic organ prolapse.</p> <p>23 Q. Is this the Clave 2010 paper?</p> <p>24 A. Correct.</p> <p>25 Q. Okay.</p>

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<p>1 (Exhibit 21 marked.)</p> <p>2 Q BY MR. SNELL: I've given you</p> <p>3 Exhibit 21. This is the paper we were referencing</p> <p>4 by Clave; correct?</p> <p>5 A. Correct.</p> <p>6 Q. Okay. This is the paper where they</p> <p>7 start out with 100 explants and they only</p> <p>8 subjected 84 of them to scanning electron</p> <p>9 microscopy; correct?</p> <p>10 A. Well, there were 100 explants, and I'd</p> <p>11 have to look through how many got evaluated with</p> <p>12 SEM. I don't recall the exact number. If you say</p> <p>13 it's 82, I'm okay with that.</p> <p>14 Q. 84.</p> <p>15 A. 84.</p> <p>16 Q. I wouldn't misrepresent to you. Right</p> <p>17 there.</p> <p>18 A. Okay. I got it.</p> <p>19 Q. You go it?</p> <p>20 A. Um-hum. Thank you.</p> <p>21 Q. Under SEM analysis, it found that less</p> <p>22 than half of the implants had this surface</p> <p>23 cracking; correct?</p> <p>24 A. It's an extremely high number, yes.</p> <p>25 Q. There were 35 out of 84?</p>	<p>1 I read that correctly; didn't I?</p> <p>2 A. I didn't see where you're reading.</p> <p>3 Q BY MR. SNELL: Right here.</p> <p>4 A. 266 or 267?</p> <p>5 Q. 266 at the bottom right.</p> <p>6 A. Oh, yes. I see it now. Yes. I'm</p> <p>7 sorry.</p> <p>8 Q. So when they try to do the other</p> <p>9 testings, the FTIR, the DSCs, they did not confirm</p> <p>10 degradation; correct?</p> <p>11 MR. CARTMELL: Object to the form.</p> <p>12 Misstates the statement.</p> <p>13 A. Again, I'd have to see where you're</p> <p>14 reading. I don't know where this is coming from.</p> <p>15 Q BY MR. SNELL: This is a question to</p> <p>16 you based on this study.</p> <p>17 A. Again, I'd have to -- it's been a</p> <p>18 while since I've gone over this paper. So I'd</p> <p>19 have to find all the nuances you're discussing. I</p> <p>20 mean, they describe degradation. They describe</p> <p>21 cracking, and to me that's degradation.</p> <p>22 But the exact etiology of it, I don't</p> <p>23 recall from the study what they came up with.</p> <p>24 Q. Well, when you see this cracking, that</p> <p>25 could be polypropylene or something other than</p>
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<p>1 A. Yeah. That's -- that's a worrisome</p> <p>2 number to me. I mean, it's 35 out of 80 women are</p> <p>3 having this degradation going on.</p> <p>4 Q. And besides just looking at the</p> <p>5 pictures on the SEM and seeing the cracking and</p> <p>6 saying that must be degradation, when they</p> <p>7 actually did tests to analyze and see if it was</p> <p>8 degradation, those testings did not show it was</p> <p>9 degradation; correct?</p> <p>10 A. You'd have to show me where you're</p> <p>11 referring to.</p> <p>12 Q. How about --</p> <p>13 A. Because to me, degradation is</p> <p>14 cracking, brittle --</p> <p>15 Q. 266.</p> <p>16 A. 266?</p> <p>17 Q. 266. You know that after doing the</p> <p>18 scanning electron microscopy, they subjected them</p> <p>19 to FTIR, DSC analyses; correct?</p> <p>20 A. Correct.</p> <p>21 Q. And if you look at the bottom of</p> <p>22 page 266, they reported that several hypotheses</p> <p>23 concerning the degradation of the PP are described</p> <p>24 below. None of these, particularly indirect</p> <p>25 oxidation, could be confirmed in this study.</p>	<p>1 polypropylene; correct?</p> <p>2 MR. CARTMELL: Object to the form.</p> <p>3 A. Well, all I can quote, as far as my</p> <p>4 experience, obviously I have these papers which I</p> <p>5 reviewed, but I can only correlate that</p> <p>6 macroscopically to my surgical experience. When I</p> <p>7 take out these meshes, which I did, it happened to</p> <p>8 be a TVT-Secur last week. Where you hold it, it's</p> <p>9 brittle, it cracks, it breaks, it's sharp; it</p> <p>10 pokes the finger. Okay. To me that is</p> <p>11 degradation.</p> <p>12 Now, on the microscopic level, you</p> <p>13 know, I don't know what exactly they call and what</p> <p>14 specific words they use to describe that process.</p> <p>15 Q BY MR. SNELL: They didn't say it was</p> <p>16 brittle and broke and cracked in your fingers in</p> <p>17 Clave; correct?</p> <p>18 A. No, they didn't say that. I'm saying</p> <p>19 that's what me and my daily experience, including</p> <p>20 just last week -- that's what I feel, and that's</p> <p>21 what I'm calling degradation of the product.</p> <p>22 Q. Clave and them show pictures of</p> <p>23 scanning electron microscopy with surface</p> <p>24 cracking?</p> <p>25 A. Yes. But none of these are TVT, you</p>

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<p>1 said. So this is a very important study. Seems 2 like they're raising red flags. 3 Next step is Ethicon needs to study it 4 with their specific product. 5 Q. And in Clave the explants have been 6 explanted because of reported complications; 7 correct? 8 A. I believe so, yes. 9 Q. There was no control group in this 10 study of explants for which there was no 11 complication reported; correct? 12 A. Well, yeah, the complication was a 13 manifestation of underlying pathology. So, no, 14 you don't have a control because you're not going 15 to go operate on women who do not have a 16 complication yet. 17 Q. And so the authors were unable to 18 state whether or not this amount and this type of 19 surface cracking is something that occurs in 20 non-explanted meshes? 21 A. I mean, you're really narrowing down 22 the focus of this. Again, it's not a TVT product, 23 but they were not able to say -- I guess, I'm not 24 really following your question. I'm sorry. 25 Q. What I was getting at is on page 269,</p>	<p>1 vaginal mesh and tape fibers explants in women, 2 okay. And that included TVT. They were removed 3 four to seven years after, and it demonstrated 4 degradation on SEM, and surface cracks, which 5 corresponds to my clinical experience. 6 Q. In these seven explants, was there any 7 oxidation found of the TVT mesh? 8 A. Oxidation is the process by which you 9 get degradation. So in order to study for 10 oxidation, you have to do some pretty 11 sophisticated chemical studies on the microscopic 12 level as far as what macrophages are doing. I 13 don't know -- I'm not an expert on how exactly 14 that would be accomplished. But if there's 15 degradation, I know there's been an inflammatory 16 response, which inflammatory response causes 17 oxidation, is one of the main reasons with 18 peroxides, hypochloric acid, et cetera. 19 Q. Has the reported degradation in these 20 seven explants been confirmed in any standardized 21 test, such as chemical analyses? 22 A. I'm unaware. I have to go back to the 23 study and see what they've done from that. From 24 my angle as a surgeon, I would want the company 25 then to go back and look at some of this stuff for</p>
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<p>1 they say, "For obvious ethical reasons this study 2 did not provide the opportunity to analyze vaginal 3 implants from non-pathological situations. 4 Therefore, prediction of normal in vivo material 5 aging and the range of consequences in the 6 clinical state beyond the observed samples is not 7 possible." 8 A. That is correct. 9 Q. Okay. Can you point to any clinical 10 studies, any studies on the TVT device to treat 11 women that showed degradation of that TVT mesh? 12 And if you're looking at your report, 13 just tell me what page so I can -- 14 A. Page 13. 15 Q. Give me a second. Okay. 16 A. Specifically if you limit it to just 17 TVT, obviously I quote multiple different studies 18 looking at polypropylene and the foreign body 19 response, the inflammatory response, the 20 degradation, you have Mary, et al., Costello, 21 Clave, Wood. But on page 15 at the very top, the 22 first full sentence says, "In 2015 seven 23 implants." And that is -- if you look down at 24 reference 11, it's a Russian name, I think. 25 T-z-a-r-t-z-e-v-a. In-depth nano-investigation of</p>	<p>1 me. 2 Q. Are there any studies that you're 3 aware of on the TVT device that correlate and show 4 that a particular complication was caused by 5 degradation? 6 A. Well, no. Degradation is part of the 7 cascade of events. You have an implantation of a 8 product that causes a foreign body response and 9 inflammatory response, which then the immune 10 system comes in with the various different dumping 11 of various different product to try and to 12 eliminate the foreign body, infection, and then 13 degradation occurs. 14 So you're not going to find something 15 where it's just degradation. It's a cascade of 16 events. 17 Q. Is there any clinical literature that 18 shows any complications are caused by degradation? 19 A. Well, I would say every study that 20 there's a vaginal erosion or extrusion is evidence 21 of degradation. Yeah, every time that I do an 22 exam on a patient and find this brittle, cracking, 23 hard mesh that is evidence of degradation. 24 Q. Are there any studies that report 25 degradation played any kind of role in a vaginal</p>

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<p style="text-align: right;">Page 250</p> <p>1 erosion or extrusion following a TVT?</p> <p>2 A. Well, yeah, this T-z-a-r-t-z-e-v-a on</p> <p>3 page 15. There are seven explants, including TVT,</p> <p>4 that were removed after implantation. Okay. So</p> <p>5 some sort of complication. And they found</p> <p>6 degradation there.</p> <p>7 (Exhibit 22 marked.)</p> <p>8 MR. CARTMELL: Just so you know,</p> <p>9 Doctor, for the record, a lot of times people call</p> <p>10 it the Zimmern study. It's easier to the</p> <p>11 pronounce.</p> <p>12 THE DEPONENT: Yeah. Phillippe at UT</p> <p>13 Southwestern.</p> <p>14 Q BY MR. SNELL: This is the paper you</p> <p>15 were referencing?</p> <p>16 A. Correct. It's an abstract.</p> <p>17 Q. It's T-z-a-r-t-z-e-v-a.</p> <p>18 A. Yeah. It's Zimmern. Phillippe</p> <p>19 Zimmern at Utah Southwestern's paper.</p> <p>20 Q. And this wasn't seven TVT devices as</p> <p>21 you put in your report; was it?</p> <p>22 A. No. I said including the TVT. So not</p> <p>23 all were TVT.</p> <p>24 Q. Right. In fact, how many of these</p> <p>25 were TVTs?</p>	<p style="text-align: right;">Page 252</p> <p>1 different devices; correct?</p> <p>2 A. That's right. That's five different</p> <p>3 devices. So TVT could be three of them. What I'm</p> <p>4 saying is this particular abstract does not break</p> <p>5 it down into which one is which.</p> <p>6 Q. And you don't have a clue then as to</p> <p>7 whether one was a TVT or two or three; correct?</p> <p>8 A. As I've stated, the abstract does not</p> <p>9 state that.</p> <p>10 Q. And this abstract doesn't state what</p> <p>11 complications, if any, occurred with the TVT;</p> <p>12 correct?</p> <p>13 A. No. It states they were explanted for</p> <p>14 some reason.</p> <p>15 Q. And you note in this study they looked</p> <p>16 for peaks of oxidation, and they didn't find any;</p> <p>17 right?</p> <p>18 A. Okay. You know, they did or didn't.</p> <p>19 Immaterial to me because it shows degradation.</p> <p>20 Degradation can occur because of multiple</p> <p>21 different reasons, but they didn't find it on this</p> <p>22 particular study.</p> <p>23 Q. And they didn't try to say the</p> <p>24 clinical effect, if any, of a 7-nanometer degree</p> <p>25 of surface cracking; correct?</p>
<p style="text-align: right;">Page 251</p> <p>1 A. I don't know if it actually says.</p> <p>2 Seven explants. But I don't think they break it</p> <p>3 down into what -- which one has what.</p> <p>4 Q. Well, they had a Gynemesh; correct?</p> <p>5 A. Correct.</p> <p>6 Q. And that's not a TVT retropubic</p> <p>7 device; correct?</p> <p>8 A. No. It's an Ethicon product.</p> <p>9 Q. Then they had a TVT; correct?</p> <p>10 A. Yes.</p> <p>11 Q. They identify one TVT in this study</p> <p>12 you cite; right?</p> <p>13 MR. CARTMELL: Object to the form.</p> <p>14 Misstates the paper.</p> <p>15 A. Again, I'd have to see where it is.</p> <p>16 Q BY MR. SNELL: Well, you cite to it,</p> <p>17 Doctor. So I'm telling you, they cite to one TVT</p> <p>18 in this study; right?</p> <p>19 MR. CARTMELL: That's not what it</p> <p>20 says. It misstates the paper.</p> <p>21 A. That's not what it -- it says seven</p> <p>22 explants were studied covering a range of</p> <p>23 currently MT devices, Gynemesh, TVT, TOT, Sparc,</p> <p>24 and mini sling.</p> <p>25 Q BY MR. SNELL: So that's five</p>	<p style="text-align: right;">Page 253</p> <p>1 A. Well, no, you have to extrapolate.</p> <p>2 There was a complication on all seven of these.</p> <p>3 They had degradation. They had cracking.</p> <p>4 Something went wrong. Was it infection? Was it</p> <p>5 pain? Extrusion? Contraction? Dyspareunia. I</p> <p>6 don't know. I'm just going -- they don't state in</p> <p>7 this paper, in this abstract.</p> <p>8 Q. Do you believe that there are any</p> <p>9 clinically significant complications that occur</p> <p>10 because of degradation?</p> <p>11 A. Yes.</p> <p>12 Q. And where do you identify them in your</p> <p>13 report? I'm sorry.</p> <p>14 A. That is in the section on Degradation,</p> <p>15 beginning on page 13 through top of 16.</p> <p>16 Q. So what specific complications, if</p> <p>17 any, arise because of degradation?</p> <p>18 A. Well, that's what we've talked about</p> <p>19 multiple times here. Degradation is one of the</p> <p>20 steps of the problems. It starts with</p> <p>21 implantation of a foreign body in a contaminated</p> <p>22 environment that creates inflammation, foreign</p> <p>23 body response. Macrophages come in. They dump</p> <p>24 their hydrogen peroxide, hypochloric acid. The</p> <p>25 product breaks down. It creates more of an</p>

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<p>1 inflammatory process. And it's a vicious cycle, 2 which leads to then scarring, contraction, scar 3 plate, dyspareunia, pelvic pain, urethral erosion, 4 bladder erosion. 5 So degradation is one of the steps of 6 this cascade. 7 Q. Are you aware of any reliable 8 scientific studies that show the degree to which 9 degradation causes any of these complications you 10 just identified as compared to surgical technique, 11 patient factors or any other causal elements? 12 A. See, that's exactly what I've been 13 trying to state this entire time. The whole 14 device, as marketed, is bad because surgeons play 15 a role. The patient may or may not. I think 16 that's questionable. We talked about that 17 already. I can't find an identifiable source 18 there. But then you have a bad product put in. 19 So the whole thing is bad. It's 20 multifactorial reasons why certain number of these 21 patients have devastating complications. 22 Q. If a patient has a mesh exposure, do 23 you assume that degradation was a cause? 24 A. Depends partly on when it occurred. 25 However, I believe Clave said it was independent</p>	<p>1 on. 2 Q. So that's what I'm asking you then, 3 okay? 4 How do you know which exposures 5 degradation played a role in, when in Clave they 6 didn't even see degradation, except in 45 percent 7 of them? 8 A. Okay. Then -- I mean -- 9 Q. That's a scientific question I'm 10 getting at. 11 A. Well, yes and no with that. So 12 45 percent of the patients, based on Clave, had 13 degradation and complications. That means the 14 other 55 had other factors, surgical, implantation 15 technique, roping, curling, whatever, to cause 16 complications. For myself, as a surgeon who takes 17 care of these patients, I ultimately don't care 18 what causes the problem. I've got a problem I've 19 got to deal with. 20 So if we want to base it upon Clave, 21 45 percent of these complications could have 22 occurred due to degradation. It's 45 percent of 23 patients who have been damaged due to degradation 24 of the product. 25 Q. Is that an opinion you hold</p>
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<p>1 of time of implantation that they found their 2 degradation. The longer it's in, intuitively and 3 based upon the data and based upon like 4 Klosterhalfen says 15 years, degradation 5 contraction continue, that the longer it's in, 6 there's going to be more problems with it. 7 Q. Well, Clave, they didn't even find 8 surface cracking in half of the explants. 9 A. But they found it in half. So tell a 10 patient, great, half of you aren't going to have 11 it at that point in time, but the other half are. 12 Q. Maybe we're not communicating. 13 We've already gone through Clave, and 14 it didn't show degradation or surface cracking in 15 more than half of the implants. 16 A. It was like 55 percent or something 17 like that, or in that ballpark. 18 Q. Right. Right. 19 So in those 55 percent, right, some of 20 those patients would have had exposures; right? 21 A. Possibly. I don't believe the article 22 states it. 23 Q. Yet they didn't see surface cracking; 24 right? 25 A. So that means something else was going</p>	<p>1 45 percent -- 2 A. No. 3 Q. -- of exposures occur because of 4 degradation? 5 A. No, I don't. We're saying based upon 6 the Clave study. I have yet to see -- and this 7 would be a very good study to be done, and it 8 should be done by Ethicon, if there's a concern 9 and they want to take care of patients and prevent 10 women from being damaged of studying these things. 11 Q. But I'm here to learn your opinion; 12 right. 13 What percent of the women who have an 14 exposure is that caused by degradation? 15 A. I guess -- 16 Q. If you can't say or you don't know, 17 tell me that. But if you have a number, then I 18 want to know the methodology by which you come 19 to -- come to that number. 20 A. If I have a patient who is seeing me 21 two or three days after a mesh sling with 22 exposure, that's not due to degradation, okay. 23 Q. That's her wound hasn't healed up? 24 A. That's right. 25 Q. Maybe it was placed superficially;</p>

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<p>1 correct?</p> <p>2 A. Within a couple of days, that is not</p> <p>3 the mesh causing -- now, it will impair healing,</p> <p>4 because there's a foreign body reaction to things.</p> <p>5 But it's not due to degradation.</p> <p>6 Q. Well --</p> <p>7 A. If somebody is occurring longer than</p> <p>8 that, let's say beyond the initial healing period.</p> <p>9 Six weeks is traditionally where the body will be</p> <p>10 at roughly 98 percent of its strength. That's our</p> <p>11 usual, going by that six weeks. Beyond that, if</p> <p>12 exposure or an event like that occurs, degradation</p> <p>13 in my opinion is going to be one of the main</p> <p>14 underlying factors for it, in combination with the</p> <p>15 infection, inflammatory response.</p> <p>16 Q. And what's the methodology for that</p> <p>17 statement?</p> <p>18 A. Exact -- based upon the literature and</p> <p>19 my clinical experience on a daily basis, including</p> <p>20 in the past two weeks, four -- three TVT and one</p> <p>21 TVT-Secur patient I dealt with.</p> <p>22 Q. Let's talk about the literature</p> <p>23 because I can't go and look at your charts, okay.</p> <p>24 In the literature, what studies show</p> <p>25 that if an exposure occurs beyond six weeks did</p>	<p>1 patients who have mesh who have devastating</p> <p>2 complications, that's a statement you'd made</p> <p>3 earlier; correct?</p> <p>4 A. Multiple times that's based on my</p> <p>5 clinical experience in talking and discussing it</p> <p>6 with surgical colleagues.</p> <p>7 Q. So you're not relying on any</p> <p>8 literature to report the rates of devastating</p> <p>9 complications with TVT retropubic; correct?</p> <p>10 MR. CARTMELL: Not relying on what?</p> <p>11 Object to the form of that.</p> <p>12 A. No. I think certain patients --</p> <p>13 certain patients.</p> <p>14 Certain studies like Hou, et al.,</p> <p>15 which was also Phillippe Zimmern, who I personally</p> <p>16 talked to about his paper, where they had slings,</p> <p>17 where after -- they had only removed for pain.</p> <p>18 19 percent had persistent pain. Just to beat you</p> <p>19 to the punch, they did not break it down into TVT</p> <p>20 or not.</p> <p>21 Q. BY MR. SNELL: And they also didn't</p> <p>22 report a denominator from which all those patients</p> <p>23 were drawn from; correct?</p> <p>24 A. They did not. That denominator, as</p> <p>25 far as I know, is not known.</p>
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<p>1 degradation play a major role, I think you said?</p> <p>2 A. Then we go back -- let's go back to</p> <p>3 Clave then. And we've said -- we've admitted</p> <p>4 roughly 45 percent of those patients had</p> <p>5 degradation. Okay. So based purely and just on</p> <p>6 that paper, that will be my opinion, that</p> <p>7 45 percent for that paper.</p> <p>8 But what I'm saying is it has been</p> <p>9 inadequately studied elsewhere. Something that</p> <p>10 needs to be done.</p> <p>11 Q. Did Clave rule out other causal</p> <p>12 factors for the exposures in his study?</p> <p>13 A. I have --</p> <p>14 Q. If he did, tell me how he did it.</p> <p>15 A. No. I would have to look at the paper</p> <p>16 and see all that he's looked at.</p> <p>17 Q. This study you talk about that you</p> <p>18 think Ethicon should have done, how would you</p> <p>19 design that study?</p> <p>20 A. The basic unfortunate reality is it --</p> <p>21 I don't know if it could be done. Hence the</p> <p>22 reason why I am anti-mesh in the vagina, because</p> <p>23 you cannot safely make this thing work and cannot</p> <p>24 do it in a long-term.</p> <p>25 Q. When you say that there are some</p>	<p>1 Q. And that's an issue with case series,</p> <p>2 where you do not have a denominator, thus one</p> <p>3 cannot compute reliably the incidence; correct?</p> <p>4 A. The true incidence, unfortunately, is</p> <p>5 not known, and it needs to be known because some</p> <p>6 of these people's lives are destroyed.</p> <p>7 Q. So in a case series like you</p> <p>8 mentioned, a major limitation to that series is</p> <p>9 that it does not speak to the incidence of those</p> <p>10 complications; correct?</p> <p>11 A. I would disagree with you that it's a</p> <p>12 major limitation. It is a limit you cannot</p> <p>13 extrapolate across the board, but in his series,</p> <p>14 in a very good reconstructive surgeon's hands,</p> <p>15 19 percent of SUIs had persistent chronic pain.</p> <p>16 Q. And you don't know how many were TVT;</p> <p>17 correct?</p> <p>18 A. That is correct.</p> <p>19 Q. More likely than not, they were not</p> <p>20 going to have persistent pain; correct?</p> <p>21 MR. CARTMELL: Object to the form. I</p> <p>22 think it's vague and ambiguous. May call for</p> <p>23 speculation.</p> <p>24 A. Oh, I see what you're saying. Okay.</p> <p>25 In the follow-up of these individuals,</p>

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<p>1 there were 19 percent that had permanent pain. 2 Statically speaking, that means that you get rid 3 of the mesh, 81 percent got better. Therefore, 4 the mesh is the source for the pain. 5 MR. SNELL: Move to strike. 6 Q BY MR. SNELL: It was more likely that 7 the patients would get better as opposed to having 8 persistent pain in the study you just told me 9 about; correct? 10 A. During the duration of their 11 follow-up, 81 percent of the patients, once the 12 mesh was relieved, had resolution of their pain. 13 Q. You wrote in your report that you 14 believe that the TVT mesh is cytotoxic? 15 A. Correct. 16 Q. You saw that cytotoxicity -- that data 17 were presented to the FDA in the 510K for TVT; 18 right? I can withdraw it and clean it up. 19 Dr. Elliott, you saw that, in the 510K 20 for TVT retropubic device to treat stress 21 incontinence, Ethicon reported the cytotoxicity 22 data that you reference in your report to the FDA; 23 right? 24 A. I don't -- it's been a long time since 25 I read the 510K submission. I have to look to see</p>	<p>1 the FDA and the people what reviewed the TVT 2 retropubic device 510K with regard to their 3 determination as to whether the TVT retropubic 4 device is safe and effective? 5 A. No. I mean, I've seen that the -- 6 that the FDA has made those statements. But what 7 I'm saying is, I don't know if they've received 8 all of the documentation and then their opinions 9 on that, as far as the cytotoxicity, et cetera. 10 Q. Okay. 11 (Exhibit 23 marked.) 12 Q BY MR. SNELL: I marked as Exhibit 23 13 the FDA's statement, Considerations about Surgical 14 Mesh for SUI, 2013. 15 This is a document you're familiar 16 with? 17 A. Correct. 18 Q. And you see this is off the FDA web 19 site as well? 20 A. That is correct. 21 Q. Page last updated March 27, 2013; 22 correct? I'll show you? 23 A. Yes, I see it. 24 Q. And it says on the first page, "the 25 safety and effectiveness of multi-incision slings</p>
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<p>1 if they talk about the severely cytotoxic, marked 2 cytotoxic part of these studies. 3 Q. You know in 2013 the FDA released a 4 statement regarding synthetic slings for the 5 treatment of stress incontinence? 6 A. They had a release. 7 Q. And you saw the FDA wrote in that 8 release that the full length mid-urethral sling 9 like TVT retropubic device has been shown to be 10 safe and effective up to one year; correct? 11 A. I would have to see that study. And 12 let's just -- or not the study. But that 13 publication. But let's just say they say that 14 exactly as you did. 15 At one year. 16 Q. Right. 17 A. Again, that's the limitation of all 18 those statements. 19 Q. And has the FDA, to your knowledge, 20 ever concluded that the TVT retropubic device -- 21 that the mesh is cytotoxic? 22 A. I have not seen that in any of their 23 writings. I don't know also what information 24 they've received. 25 Q. You have not seen any documents from</p>	<p>1 is well established in clinical trials that 2 followed patients for up to one year. Longer 3 follow-up data is available in the literature, but 4 there are fewer of these long-term studies 5 compared to studies with one-year follow-up." 6 Correct? 7 A. Correct. That's what they state. 8 Q. Let me ask you this question. 9 It would be a true statement that the 10 safety and effectiveness of the Burch 11 colposuspension, the autologous slings, biologic 12 slings, cadaveric slings, all the different stress 13 incontinence options -- that the safety and 14 effectiveness of them has been assessed more, to a 15 greater volume in studies reporting on 12 months 16 or less as compared to longer term studies; 17 correct? 18 MR. CARTMELL: Object to the form. 19 A. That would be true, that most SUI 20 studies are short-term because they're easier to 21 do, and that's why the data is poor to moderately 22 poor. 23 Q BY MR. SNELL: So what you just said 24 there, let me make sure I understand you. 25 Shorter term studies assessing stress</p>

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<p style="text-align: right;">Page 266</p> <p>1 urinary incontinence surgery are easier to do than 2 longer term studies? 3 A. Correct. 4 Q. That applies across the board? 5 A. Correct. I mean, shorter term studies 6 are easier to do because they're short-term. You 7 have less patient loss to follow-up those things. 8 Q. What studies, if any, in women show 9 that cytotoxicity causes any complications with 10 the use of TVT retropubic device? 11 A. There have been none because the issue 12 of cytotoxicity has not been released to the 13 general public. Therefore, someone is not going 14 to study that if they don't even know it exists. 15 Q. Do you know the 510K documents on TVT 16 are publicly available at the FDA and available 17 through a Google search on the web sites? 18 A. They may be. I don't -- I don't know 19 because I don't search that. 20 Q. You've never attempted that search? 21 A. Not with this device. I've done it 22 with the ObTape, and I couldn't find it. 23 Q. Okay. Are there any complications 24 that you believe are due to cytotoxicity? 25 A. Possible --</p>	<p style="text-align: right;">Page 268</p> <p>1 60 months follow-up. 2 Of that 2.4 percent, can you say how 3 many of those 17 patients had the defective 4 vaginal healing because of cytotoxicity, or is 5 that known? 6 A. That has not been studied to date, 7 because as I mentioned, I didn't even know the 8 cytotoxicity report even existed until I got 9 involved in this. So no one out in the community, 10 our physicians, researchers are going to know that 11 exists. They're not going to study it. 12 Q. What percent of TVT retropubic devices 13 is the mesh cytotoxic? 14 A. Well, from what they state here, if 15 this TVT is studied and has been shown to have 16 marked cytotoxicity or severely cytotoxic in these 17 two references and that mesh is put in the 18 patient, then 100 percent of those have the 19 potential for cytotoxicity. 20 Q. All right. So if 100 percent have a 21 cytotoxic mesh, why is it that 97.6 percent in the 22 Wang study who were followed out beyond 60 months 23 didn't have any defective vaginal healing? 24 A. It's going to be, again, 25 multifactorial. The vaginal healing, the duration</p>
<p style="text-align: right;">Page 267</p> <p>1 Q. Let me make sure because I want to 2 focus on TVT, not leave a vague question out there 3 because we were last talking about ObTape. 4 So for the TVT retropubic device, are 5 there complications which you believe are caused 6 by cytotoxicity? 7 A. In theory, possibly all of them, 8 because cytotoxicity is cell death. Cell death 9 will increase the foreign body response, the 10 inflammatory response, subsequently increase the 11 degradation, cracking, increase pain, increase the 12 potential for infection. I'm saying possibly. It 13 could be. 14 Q. Okay. 15 A. That has not been studied to date. 16 Q. Okay. For example, you pointed me to 17 the Wang paper earlier, and we looked at it, and 18 there was a 2.4 percent rate of exposure; right? 19 A. There was 17 out of 700 that had 20 impaired vaginal healing. And I can't recall the 21 data beyond that. 22 Q. It was 2.4 percent? 23 A. Okay. I remember the 2.4 percent. 24 Q. Okay. So working with that number, 25 2.4 percent, and we looked and there was more than</p>	<p style="text-align: right;">Page 269</p> <p>1 of follow-up, is smoking going to play a role, 2 obesity, impaired vaginal status. And, again, 3 what's going to be these people 15, 20, 30 years 4 from now. 5 MR. SNELL: Move to strike as 6 nonresponsive. 7 Q. BY MR. SNELL: My question was: If 8 100 percent of people have the cytotoxic TVT 9 retropubic mesh, why is it that 97.6 percent of 10 the patients in Wang did not have the defective 11 vaginal healing? 12 A. See the -- not to be critical, but 13 your logic is impaired. 100 percent of people who 14 smoke don't get lung cancer. 100 percent of 15 people exposed to asbestos don't get mesothelioma. 16 100 percent exposed to TVT aren't going to have 17 those devastating complications, but certain ones 18 do. 19 Q. And that's what I'm trying to 20 understand and test here. All right. 21 What is it about the 97.6 percent of 22 the patients who didn't have defective vaginal 23 healing that led this cytotoxic mesh to have no 24 role or no effect on the -- 25 A. Okay. We decreased it down. You said</p>

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<p>1 defective vaginal healing.</p> <p>2 Q. I was trying to use the words you</p> <p>3 said.</p> <p>4 A. You're correct; 2.4 percent had</p> <p>5 defective vaginal healing. That is just one of</p> <p>6 the complications. Not all cytotoxicity or</p> <p>7 degradation is going to go just to mesh extrusion.</p> <p>8 I'm talking pain, contraction, roping, the</p> <p>9 degradation process. Pelvic pain, vaginal pain,</p> <p>10 dyspareunia.</p> <p>11 So they are just saying, just in this</p> <p>12 limiting it, 2.4 percent had defective vaginal</p> <p>13 healing. Okay. So that's narrowing the number I</p> <p>14 talked about before, okay. I cannot answer the</p> <p>15 question as to why don't all. All I know is that</p> <p>16 to me this is a red flag and patients and doctors</p> <p>17 need to be warned of that possible cytotoxicity.</p> <p>18 Q. For example, we looked at the number</p> <p>19 of patients who reported dyspareunia and there was</p> <p>20 four out of that group.</p> <p>21 A. Five complained of pain. Four</p> <p>22 complained of dyspareunia, and then five</p> <p>23 complained of vaginal bleeding.</p> <p>24 Q. Right. So for the dyspareunia,</p> <p>25 right -- we addressed this somewhat. I will</p>	<p>1 be studied.</p> <p>2 Q BY MR. SNELL: Okay. That was my</p> <p>3 question.</p> <p>4 Of -- and I was really focused on</p> <p>5 dyspareunia. Of the four patients with</p> <p>6 dyspareunia, you can't say, reliably,</p> <p>7 scientifically, which if any of those four were</p> <p>8 caused by cytotoxicity; correct?</p> <p>9 A. No. You are correct because all I can</p> <p>10 say is there was some defect in the product that</p> <p>11 caused this. I cannot attribute that just to</p> <p>12 cytotoxicity.</p> <p>13 Q. And Wang did not rule out other</p> <p>14 factors besides the mesh; did he?</p> <p>15 A. I don't recall Wang giving a specific</p> <p>16 opinion on that, what necessitated.</p> <p>17 Q. How would you design a study like you</p> <p>18 state Ethicon should do with regard to</p> <p>19 cytotoxicity to see what effect, if any, it would</p> <p>20 have on complications for women receiving the TVT</p> <p>21 retropubic device for stress incontinence?</p> <p>22 A. You cannot ethically construct a study</p> <p>23 of putting a product in that has the possibility</p> <p>24 of cytotoxicity in a patient for a quality of life</p> <p>25 study. You can't do it. It would never get</p>
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<p>1 represent to you I calculated that, and it's</p> <p>2 0.56 percent. Okay. 4 out of 700.</p> <p>3 For that 0.56 percent of patients who</p> <p>4 had dyspareunia, is there a way to scientifically</p> <p>5 reliably say, which, if any of them, that was</p> <p>6 caused by cytotoxicity? And if there is, I want</p> <p>7 to know the methodology by which you would</p> <p>8 conclude that.</p> <p>9 A. That would require a study by Ethicon</p> <p>10 to do that. And so all I know is we have a red</p> <p>11 flag. We have marked cytotoxicity. We have</p> <p>12 complication. These are just limiting to the</p> <p>13 specific one. I cannot point to a paper and say</p> <p>14 that because then it has not been studied because</p> <p>15 individuals didn't know to study it. It needs to</p> <p>16 be studied, though.</p> <p>17 Q. So I think in fairness, the answer to</p> <p>18 my question was, no, you don't know that; correct?</p> <p>19 MR. CARTMELL: Objection. Asked and</p> <p>20 answered. He just answered your question.</p> <p>21 A. No. And I will reiterate just what I</p> <p>22 said again. Cytotoxicity is a red flag of</p> <p>23 something going on. We know there's cytotoxicity</p> <p>24 there. How much of a role it plays in all the</p> <p>25 other complications, I don't know. That needs to</p>	<p>1 approved and no woman would accept it.</p> <p>2 Q. Am I correct that for the pore size of</p> <p>3 the TVT mesh you cannot reliably say</p> <p>4 scientifically what complications are caused due</p> <p>5 to pore size in TVT patients?</p> <p>6 MR. CARTMELL: Object to the form.</p> <p>7 A. As I've stated multiple times, as</p> <p>8 outlined in my report, we have an overall system</p> <p>9 design failure.</p> <p>10 Specifically small pore, what role is</p> <p>11 that playing in percentage of the complications.</p> <p>12 No, I cannot state that.</p> <p>13 Q BY MR. SNELL: You have not studied</p> <p>14 the rates of complications of stress urinary</p> <p>15 incontinence slings to see whether there is a</p> <p>16 statistically significant different rate of</p> <p>17 complications that occurs dependent upon pore</p> <p>18 size; correct?</p> <p>19 A. You are partly correct. However, we</p> <p>20 do know from the hernia mesh data and the Vypro</p> <p>21 mesh data that complications can be reduced with a</p> <p>22 large poor lightweight. It has not been extended</p> <p>23 down into the TVT like it should have been. So</p> <p>24 you are correct. That data does not exist and it</p> <p>25 should exist.</p>

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<p style="text-align: right;">Page 274</p> <p>1 Q. Actually, that data do exist to some 2 degree in the application of stress urinary 3 incontinence because there are data like the 4 Cochrane Reviews that show that multifilament 5 meshes have higher complication rates than 6 monofilament meshes; correct?</p> <p>7 A. Yes. But we're talking about the TVT 8 here. And I'm talking about lightweight hernia 9 mesh. You know, Ethicon employees all agree, 10 lightweight, small -- or large pore reduce 11 complications. The Cochrane has nothing to do 12 with lightweight, large pore meshes. It doesn't 13 exist, as far as I know, for slings.</p> <p>14 Q. The multifilament meshes assessed in 15 the Cochrane Review that had higher rates of 16 complications compared to the monofilament meshes 17 like TVT have a smaller pore size than the TVT 18 mesh; correct?</p> <p>19 A. No. You are correct, but we're 20 talking -- yes, I agree with you. 21 The ObTape, the ProteGen, the 22 Gortexes, the Amid 3's have higher implications 23 than TVT. I agree with you. But what I'm saying 24 is the next level up above TVT, the lightweight, 25 large pore meshes, it does not exist. The</p>	<p style="text-align: right;">Page 276</p> <p>1 body.</p> <p>2 Q. No surgeon in the world that you're 3 aware of has ever taken a larger pore, lighter 4 weight hernia mesh, cut it down to 1.1 5 centimeters, put it in a sheath and placed it 6 retropubically, like the TVT retropubic device; 7 correct?</p> <p>8 A. I am unaware of anybody doing that. 9 Including Ethicon.</p> <p>10 Q. Therefore, you are unaware of any 11 studies in the application of a stress urinary 12 incontinence tape that show that when put in that 13 configuration and used as the TVT is, 14 retropubically, with the passage of trochars, that 15 there is a lower complication rate in stress 16 incontinent women; correct?</p> <p>17 MR. CARTMELL: Object to the form. I 18 believe it misstates his opinions in this case and 19 the report.</p> <p>20 Q. BY MR. SNELL: Go ahead.</p> <p>21 A. And therein lies a huge deficit of 22 what Ethicon should have done. They knew the data 23 on hernia meshes and prolapse meshes. Large pore, 24 lightweight fewer complications. They did not 25 take the next step of extrapolating that to TVT,</p>
<p style="text-align: right;">Page 275</p> <p>1 technology exists for it, but the product has not 2 been done in any studies for women in stress 3 incontinence.</p> <p>4 Q. Right. Okay. So those larger pore, 5 lighter weight meshes have not been cut down to 6 1.1 centimeters, put into sheaths and tested by 7 anyone; correct?</p> <p>8 A. That is correct. In my opinion it 9 should have been.</p> <p>10 Q. All right. What physicians and 11 surgeons -- well, strike that. 12 If physicians and surgeons wanted to 13 test larger pore, lighter weight hernia meshes in 14 the application of stress incontinence, couldn't 15 they cut slings made of ULTRAPRO and test it for 16 incontinence?</p> <p>17 A. I can't speak to what surgeons could 18 or could not do.</p> <p>19 Q. Well, you cut mesh and put it in the 20 body however you wanted; didn't you?</p> <p>21 A. No.</p> <p>22 Q. You didn't do that for sacrocolpopexy?</p> <p>23 A. I configured an already Y-shaped mesh. 24 I did not take something and create something new. 25 I just configured it to fit into the patient's</p>	<p style="text-align: right;">Page 277</p> <p>1 because, as they said, now their TVT data no 2 longer holds up. So they made a decision not to 3 do that.</p> <p>4 Q. BY MR. SNELL: Well, you would 5 criticize Ethicon for wanting to have a product 6 that has longer term data than all the other 7 meshes out there, including ones you, yourself, 8 have used?</p> <p>9 MR. CARTMELL: Objection.</p> <p>10 Argumentative.</p> <p>11 A. Well, I have no problem with them 12 having long-term studies out there, but I'm saying 13 they're not focused on safety. And I'm saying if 14 they knew, if a corporation knew that there were a 15 better product available and they chose not to, 16 purely for marketing, that is unethical, 17 unacceptable.</p> <p>18 Q. BY MR. SNELL: How do they know it's 19 better in the application of stress urinary 20 incontinence when the sling is only 1.1 21 centimeters?</p> <p>22 A. They should --</p> <p>23 MR. CARTMELL: Object to the form. I 24 don't understand the question.</p> <p>25 A. No.</p>

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<p>1 MR. SNELL: I mean, you're -- I mean,</p> <p>2 what you're talking about is Ethicon's state of</p> <p>3 mind, and that will not fly with this judge. So</p> <p>4 I'm going to withdraw that question.</p> <p>5 MR. CARTMELL: Let's take a break.</p> <p>6 MR. SNELL: That's fine.</p> <p>7 (Recessed from 4:25 p.m. to</p> <p>8 4:42 p.m.)</p> <p>9 MR. SNELL: You do know that I'm here</p> <p>10 to question him on his New Jersey report as well?</p> <p>11 MR. CARTMELL: No, I didn't know that.</p> <p>12 MR. SNELL: Ben didn't tell you that?</p> <p>13 MR. CARTMELL: Hum-um.</p> <p>14 MR. SNELL: He said he wanted it all</p> <p>15 done in one sitting. So --</p> <p>16 MR. CARTMELL: He told me next week in</p> <p>17 Minneapolis.</p> <p>18 MR. SNELL: That's only case specific</p> <p>19 on Watkins. I'm doing the New Jersey general</p> <p>20 stuff today.</p> <p>21 MR. CARTMELL: Okay.</p> <p>22 MR. SNELL: That's what they told me.</p> <p>23 MR. CARTMELL: I'm not doing that. If</p> <p>24 you're telling me you're going longer than</p> <p>25 7 hours --</p>	<p>1 there at 6:00, I'm going to get my brains beat in.</p> <p>2 I'm not doing that.</p> <p>3 MR. SNELL: Well, then we're going to</p> <p>4 have to agree that whenever I can make it and the</p> <p>5 doctor make it, we'll do the New Jersey general</p> <p>6 TVT portion.</p> <p>7 MR. CARTMELL: Well, that's fine. But</p> <p>8 I'm not --</p> <p>9 MR. SNELL: Because the person who's</p> <p>10 deposing him in Watkins --</p> <p>11 MR. CARTMELL: Look, there's --</p> <p>12 MR. SNELL: Let me just say something.</p> <p>13 MR. CARTMELL: This is ridiculous that</p> <p>14 you take 7-hour depositions.</p> <p>15 MR. SNELL: The person disposing him</p> <p>16 in Watkins is only case specific. That was all</p> <p>17 agreed to and hammered out --</p> <p>18 MR. CARTMELL: Nobody told me that.</p> <p>19 MR. SNELL: -- between Ben and</p> <p>20 everybody in these big mass emails. All right.</p> <p>21 Well, let's just -- let's jump on it, okay.</p> <p>22 MR. CARTMELL: Okay.</p> <p>23 MR. SNELL: We'll find something that</p> <p>24 works. But I'm telling you -- and you know it. I</p> <p>25 know you're tied up and I'm tied up, through the</p>
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<p>1 MR. SNELL: Yeah.</p> <p>2 MR. CARTMELL: -- I ain't doing that.</p> <p>3 MR. SNELL: Well, why didn't Ben tell</p> <p>4 you that, because that's the agreement.</p> <p>5 MR. CARTMELL: Nobody told me that.</p> <p>6 MR. SNELL: That's the agreement I put</p> <p>7 in the emails, too. Ben was having --</p> <p>8 MR. CARTMELL: This was the</p> <p>9 consolidation deposition.</p> <p>10 MR. SNELL: Right. And then but Ben</p> <p>11 said, but you need to do his New Jersey generally</p> <p>12 TVT at the same sitting because Watkins case</p> <p>13 specific is next week. And I said, okay, I'll</p> <p>14 start that after I finish the design defect. It's</p> <p>15 all in the emails. I'm surprised he did not tell</p> <p>16 you that.</p> <p>17 MR. CARTMELL: He didn't tell me and</p> <p>18 I'm not doing it.</p> <p>19 MR. SNELL: Is that on the record. I</p> <p>20 mean, because I came here and flew here to do</p> <p>21 both. And I'm not available next weekend, okay,</p> <p>22 because I have my own experts.</p> <p>23 MR. CARTMELL: I'm not available</p> <p>24 tonight, and I -- I agreed to do this, and I have</p> <p>25 something I have to be at at 6:00, and if I'm not</p>	<p>1 5th, okay. But I'm here today, prepared to do the</p> <p>2 New Jersey general after this one.</p> <p>3 MR. CARTMELL: Well, I'm not.</p> <p>4 MR. SNELL: I know. I know.</p> <p>5 MR. CARTMELL: I'm not doing that.</p> <p>6 I'm not doing 9 hours --</p> <p>7 MR. SNELL: I don't know why they</p> <p>8 didn't tell you.</p> <p>9 MR. CARTMELL: I'm not making the</p> <p>10 doctor do 9 hours of deposition. That's</p> <p>11 ridiculous. This is crazy. We're, again, going</p> <p>12 over stuff that I think you even covered in his</p> <p>13 first depo.</p> <p>14 MR. SNELL: I've only deposed him on</p> <p>15 Prolift.</p> <p>16 MR. CARTMELL: But that doesn't</p> <p>17 matter. A lot of this stuff has been talked</p> <p>18 about.</p> <p>19 MR. SNELL: No. But this is in the</p> <p>20 application of the design of TVT for stress</p> <p>21 incontinence. That was the agreement.</p> <p>22 MR. CARTMELL: Go. You've got</p> <p>23 48 minutes.</p> <p>24 MR. SNELL: That was the agreement,</p> <p>25 okay. That's why I came here. And I'm prepared</p>

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<p style="text-align: right;">Page 282</p> <p>1 to do that.</p> <p>2 MR. CARTMELL: I wish I had known.</p> <p>3 MR. SNELL: I wish they would have</p> <p>4 told you, to be honest with you. And I wish they</p> <p>5 would have told me, because I was preparing to go</p> <p>6 out tomorrow. And as for the length of deposition</p> <p>7 being ridiculous, in New Jersey some of my experts</p> <p>8 were deposed for more than 13 hours.</p> <p>9 MR. CARTMELL: I just can't believe</p> <p>10 this. But go ahead.</p> <p>11 MR. SNELL: All right. So we'll pick</p> <p>12 it up. Are you ready, Doc.</p> <p>13 THE DEPONENT: Yes, I am.</p> <p>14 Q BY MR. SNELL: You got your report</p> <p>15 there handy?</p> <p>16 A. Yes, I do.</p> <p>17 Q. Can you just turn to page 20.</p> <p>18 A. Yes.</p> <p>19 Q. The picture there, that is not a</p> <p>20 picture of the TVT retropubic device to treat</p> <p>21 stress urinary incontinence; is that correct?</p> <p>22 A. That is correct.</p> <p>23 Q. All right. The width of whatever that</p> <p>24 mesh is is a lot more than 1 centimeter; correct?</p> <p>25 A. I don't know the dimensions on that.</p>	<p style="text-align: right;">Page 284</p> <p>1 section of my report, which I have down here</p> <p>2 starting on roughly page 17, it appears.</p> <p>3 In there I say, Ethicon's medical</p> <p>4 director stated that TVT can shrink -- generally</p> <p>5 believe TVT mesh would shrink approximately</p> <p>6 30 percent post implantation, and that is an</p> <p>7 internal document.</p> <p>8 MR. SNELL: So respectfully move to</p> <p>9 strike.</p> <p>10 Q. BY MR. SNELL: My question was: Are</p> <p>11 you aware of any clinical studies that assess the</p> <p>12 TVT in the application of stress urinary</p> <p>13 incontinence and reported that there was no</p> <p>14 shrinkage with the TVT mesh?</p> <p>15 A. That there was no shrinkage? I'm</p> <p>16 unaware of any studies that's documented no</p> <p>17 shrinkage.</p> <p>18 Q. Okay. The Vypro mesh, you're aware</p> <p>19 that -- let me back up.</p> <p>20 So you make reference to Vypro and</p> <p>21 ULTRAPRO in your report; I believe; correct?</p> <p>22 A. Vypro. I'd have to look and see with</p> <p>23 ULTRAPRO, where I put that. But Vypro, yes.</p> <p>24 Q. In the context of a hernia or animal</p> <p>25 study; correct?</p>
<p style="text-align: right;">Page 283</p> <p>1 I have to go back to the original document.</p> <p>2 Q. Well, if you look at the number of</p> <p>3 pores all the way across it, you and I can agree</p> <p>4 that that's a lot more than 1 centimeter wide;</p> <p>5 correct.</p> <p>6 MR. CARTMELL: Object to the form.</p> <p>7 A. Again, I can't say. I just don't</p> <p>8 know. I'm saying I don't know what it is. I'm</p> <p>9 not disagreeing with you. I just don't know.</p> <p>10 Q BY MR. SNELL: There's no sheath on</p> <p>11 that mesh; correct?</p> <p>12 A. That is correct.</p> <p>13 Q. And there's certainly no trochars</p> <p>14 connected to it; correct?</p> <p>15 A. That is correct.</p> <p>16 Q. And you don't know how that --</p> <p>17 whatever mesh it was stretched; is that correct?</p> <p>18 A. I'd have to go back to the original</p> <p>19 document and see what they said.</p> <p>20 Q. Okay. Are you aware of any studies</p> <p>21 that have looked at potential shrinkage with the</p> <p>22 TVT device in the application of stress</p> <p>23 incontinence treatment that report that there was</p> <p>24 no shrinkage with the TVT?</p> <p>25 A. We'd have to go to the contraction</p>	<p style="text-align: right;">Page 285</p> <p>1 A. That's correct. On page 21 of my</p> <p>2 report.</p> <p>3 Q. You know Vypro was assessed even for</p> <p>4 the application of prolapse and was found to have</p> <p>5 a greater than 10 percent exposure rate; right?</p> <p>6 A. That is correct. But it was less than</p> <p>7 the existing Gynemesh.</p> <p>8 Q. Actually it was assessed and it was</p> <p>9 found to be 17 percent and Dr. Jacquetin found</p> <p>10 that it was not tolerated by the body.</p> <p>11 A. Okay.</p> <p>12 Q. Is that correct?</p> <p>13 A. I don't recall that. I have no reason</p> <p>14 to doubt that it's incorrect.</p> <p>15 Q. Okay. And the ULTRAPRO, you're aware</p> <p>16 that that was ultimately put into the Prolift</p> <p>17 Plus, and there were mesh exposures with that mesh</p> <p>18 in the POP application; correct?</p> <p>19 MR. CARTMELL: Object to the form. Go</p> <p>20 ahead.</p> <p>21 A. Yes. Again, and that reinforces my</p> <p>22 opinion. Mesh should not be placed in the vagina.</p> <p>23 Can we just -- I'm sorry to</p> <p>24 interrupt -- deflect the curtain the opposite</p> <p>25 direction. Thank you. Feel like God there for a</p>

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<p style="text-align: right;">Page 286</p> <p>1 second; I was glowing.</p> <p>2 Q BY MR. SNELL: You know that</p> <p>3 Dr. Jacquetin in the TVM group assessed Vypro in</p> <p>4 the transvaginal mesh pelvic organ prolapse</p> <p>5 application?</p> <p>6 A. That is correct. I've read that, yes.</p> <p>7 Q. And they found that tolerance of that</p> <p>8 material was poor?</p> <p>9 MR. CARTMELL: Object to the form.</p> <p>10 You got the study. Show it to him. I think -- I</p> <p>11 think you're misstating the study.</p> <p>12 Q BY MR. SNELL: You're aware of that;</p> <p>13 correct?</p> <p>14 A. I am aware that they did look at it.</p> <p>15 I am not aware of the specific details of that</p> <p>16 study. It's been a while since I looked at that</p> <p>17 study.</p> <p>18 Q. I have it here on the computer.</p> <p>19 A. That's fine. Which name or title is</p> <p>20 it? Or who's the lead author?</p> <p>21 Q BY MR. SNELL: Denis, D-e-n-i-s.</p> <p>22 A. Okay.</p> <p>23 Q. Denis, Jacquetin. Here you better --</p> <p>24 okay. You need to maximize -- there you go?</p> <p>25 A. Oh, so it's an abstract.</p>	<p style="text-align: right;">Page 288</p> <p>1 Q. And they talk about the use of a half</p> <p>2 absorbable mesh does not seem to reduce</p> <p>3 inflammation and could even accentuate it;</p> <p>4 correct?</p> <p>5 A. That's correct. All right. And then</p> <p>6 they go on to say, "Good results of the TVT does</p> <p>7 not seem to be much modified by the additional" --</p> <p>8 okay. That's separate.</p> <p>9 Q. Your understanding --</p> <p>10 A. I have to see if that Vypro -- they</p> <p>11 mentioned a bioabsorbable, is if they have Vicryl</p> <p>12 in there --</p> <p>13 Q. Right.</p> <p>14 A. -- or a collagen base of some sort.</p> <p>15 That's associated with increased inflammation.</p> <p>16 MR. CARTMELL: Hey, put the name of</p> <p>17 that study and the citation to it on the record,</p> <p>18 please.</p> <p>19 MR. SNELL: Yeah. Denis, D-e-n-i-s,</p> <p>20 Abstract 620. It was an abstract presentation.</p> <p>21 And Dr. Jacquetin there, too. All of the study</p> <p>22 subjects coming out of Clermont-Ferrand. Abstract</p> <p>23 620 at the joint ICS/IUGA 2004 conference in</p> <p>24 Paris, France. I'll make that representation. I</p> <p>25 know that's where this is from.</p>
<p style="text-align: right;">Page 287</p> <p>1 Q. Right.</p> <p>2 A. Okay.</p> <p>3 Q. You see that they reported the</p> <p>4 tolerance was poor?</p> <p>5 A. Let me go to their conclusions.</p> <p>6 Q. Can I come around and look at it with</p> <p>7 you.</p> <p>8 A. By all means.</p> <p>9 Q. Because it's electronic, just so the</p> <p>10 record reflects -- it says in this study that</p> <p>11 tolerance of the Vypro mesh is VERY poor; correct?</p> <p>12 A. That's what it states, yes.</p> <p>13 Q. High rate of erosion, and problems of</p> <p>14 cicatrisation have been observed.</p> <p>15 A. Correct. C-i-c-a-t-r-i-s-a-t-i-o-n,</p> <p>16 which just means scars.</p> <p>17 Q. Okay.</p> <p>18 A. Contraction.</p> <p>19 Q. And it also had complications of</p> <p>20 retraction and rigidity were observed with the</p> <p>21 Vypro mesh?</p> <p>22 A. That is correct.</p> <p>23 Q. Frequently with clinical severe</p> <p>24 consequences; correct?</p> <p>25 A. That is correct.</p>	<p style="text-align: right;">Page 289</p> <p>1 THE DEPONENT: And I was at that</p> <p>2 meeting.</p> <p>3 Q BY MR. SNELL: Did you see this</p> <p>4 presentation?</p> <p>5 A. I don't recall seeing it, no.</p> <p>6 Q. And you know the Vypro mesh, it's a</p> <p>7 larger pore mesh than the mesh used in the TVT</p> <p>8 device; correct?</p> <p>9 A. It is.</p> <p>10 Q. And the Vypro mesh uses a combination</p> <p>11 of Vicryl with the Prolene polypropylene; correct?</p> <p>12 A. Again, I'd have to refresh my memory.</p> <p>13 That is my recollection. It is partially</p> <p>14 absorbable.</p> <p>15 Q. All right. The Vicryl part is what</p> <p>16 absorbs over time?</p> <p>17 A. That is correct.</p> <p>18 Q. And the Prolene polypropylene mesh is</p> <p>19 what's left behind; correct?</p> <p>20 A. That is the permanent portion of the</p> <p>21 implant, yes.</p> <p>22 MR. SNELL: Let's mark this.</p> <p>23 (Exhibit 24 marked.)</p> <p>24 Q BY MR. SNELL: Exhibit 24 is a study</p> <p>25 of various meshes, fascia, animal, cadaveric</p>

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<p style="text-align: right;">Page 290</p> <p>1 materials, and the rabbit model with implications</p> <p>2 for sling surgery; correct?</p> <p>3 A. That is correct.</p> <p>4 Q. This is a paper you were one of the</p> <p>5 authors of; correct?</p> <p>6 A. I was the lead author.</p> <p>7 Q. Okay. And this was published in the</p> <p>8 Journal of Urology?</p> <p>9 A. Correct. In 2004.</p> <p>10 Q. All right. Is the Journal of</p> <p>11 Urology -- does it have a poor peer review</p> <p>12 process?</p> <p>13 A. A poor, meaning incompetent? I</p> <p>14 mean --</p> <p>15 Q. Okay.</p> <p>16 A. As opposed to pore, p-o-r-e? You're</p> <p>17 talking poor, p-o-o-r?</p> <p>18 Q. Yes, sir, p-o-o-r.</p> <p>19 A. No. It would -- in urology, it is</p> <p>20 probably one of the most strict peer review, along</p> <p>21 with the European Urology Journal.</p> <p>22 Q. All right. So among the various</p> <p>23 things assessed, one was polypropylene mesh.</p> <p>24 Another was autologous fascia; correct?</p> <p>25 A. That is correct. And it was the Sparc</p>	<p style="text-align: right;">Page 292</p> <p>1 However, in the first 10 patients we didn't know</p> <p>2 the tensioning of this. No one had ever done it</p> <p>3 before. And so we're accounting for a lot of</p> <p>4 different factors. Is it going to -- is it going</p> <p>5 to tighten up or is it going to stretch out. We</p> <p>6 didn't know.</p> <p>7 Q. Okay.</p> <p>8 A. And that's why it's a feasibility</p> <p>9 study.</p> <p>10 Q. Okay. The last page you talk about</p> <p>11 "the polypropylene mesh has extremely low</p> <p>12 stiffness at baseline, but it demonstrated</p> <p>13 increasing stiffness with time. This phenomenon</p> <p>14 is likely caused by the ingrowth of tissues into</p> <p>15 the interstices of the mesh."</p> <p>16 A. That's correct. That's what we</p> <p>17 stated.</p> <p>18 Q. Is that an accurate statement?</p> <p>19 A. That is an accurate statement of what</p> <p>20 we found. We did not know at that point in time</p> <p>21 the potential implications of that.</p> <p>22 Q. You concluded that the biomechanical</p> <p>23 results of the current study support the use of</p> <p>24 polypropylene mesh for sling surgery relative to</p> <p>25 other non-autologous materials; right?</p>
<p style="text-align: right;">Page 291</p> <p>1 that we used.</p> <p>2 Q. And Sparc was a -- that was a</p> <p>3 monofilament polypropylene mesh; correct?</p> <p>4 A. Correct. Quite similar to TVT.</p> <p>5 Q. And there was a rapid loss of strength</p> <p>6 and stiffness in the porcine and cadaveric</p> <p>7 materials; correct?</p> <p>8 A. That is correct.</p> <p>9 Q. And the autologous fascia, as well as</p> <p>10 small intestinal submucosa demonstrated the</p> <p>11 highest rate of contraction; correct?</p> <p>12 A. In this short-term limited, yes,</p> <p>13 that's what we found.</p> <p>14 Q. Does the autologous fascia contract in</p> <p>15 the human body?</p> <p>16 A. It is reabsorbed. And remodeled is</p> <p>17 the term we usually use. As opposed to</p> <p>18 contraction.</p> <p>19 Q. I saw in your pilot study with the</p> <p>20 10 patients with the transobturator autologous</p> <p>21 sling that you reported that you placed that sling</p> <p>22 loosely in order to hopefully minimize contraction</p> <p>23 of the autologous tissues.</p> <p>24 Do you recall that statement?</p> <p>25 A. I don't recall that statement per se.</p>	<p style="text-align: right;">Page 293</p> <p>1 A. Again, that's what we stated as of</p> <p>2 2004 in our short-term study because we found the</p> <p>3 increased stiffness and thought that that would be</p> <p>4 increased as far as efficacy. And we didn't</p> <p>5 realize that that process continues.</p> <p>6 Q. You published a subsequent study in</p> <p>7 follow-up; correct?</p> <p>8 A. Correct. By Krambeck, et al.</p> <p>9 MR. SNELL: Go off the record for a</p> <p>10 second.</p> <p>11 (Exhibit 25 marked.)</p> <p>12 Q BY MR. SNELL: So-Exhibit 25, Doctor,</p> <p>13 is your follow-up study that you published in 2006</p> <p>14 in the Urology Journal; correct?</p> <p>15 A. Correct.</p> <p>16 Q. And this was a study where you found</p> <p>17 significant differences were found for</p> <p>18 inflammation, eosinophil infiltrate and</p> <p>19 inflammatory rind at 12 weeks with polypropylene</p> <p>20 mesh having the lowest degree; correct?</p> <p>21 A. That was one of our findings.</p> <p>22 Q. And that was a study looking at</p> <p>23 polypropylene mesh versus cadaveric fascia,</p> <p>24 porcine dermis, porcine small intestine submucosa,</p> <p>25 and autologous fascia; correct?</p>

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<p style="text-align: right;">Page 294</p> <p>1 A. Those were all the properties or the</p> <p>2 substances we studied.</p> <p>3 Q. All right. And you reported that the</p> <p>4 inflammation with the cadaveric fascia and porcine</p> <p>5 may cause rapid clinical deterioration compared to</p> <p>6 the autologous fascia and polypropylene mesh?</p> <p>7 A. That is correct. That was the main</p> <p>8 purpose of this study, looking at what happens to</p> <p>9 the cadaveric and porcine materials. Does the</p> <p>10 body rapidly absorb them, which we found out it</p> <p>11 did. And the polypropylene had the greatest</p> <p>12 degree of scar formation.</p> <p>13 Q. And that's one of the reasons why</p> <p>14 cadaveric fascia and porcine materials for use in</p> <p>15 the sling application never really caught on to a</p> <p>16 large degree because, with longer term follow-up</p> <p>17 surgeons found that those slings would actually be</p> <p>18 absorbed into the body; correct?</p> <p>19 A. Partly correct. The porcine, no</p> <p>20 question. The porcine dermis and then the porcine</p> <p>21 SIS, in my opinion, were horrible products. I</p> <p>22 used them and they failed miserably. It was</p> <p>23 worthless to do that. Actually worse than</p> <p>24 worthless.</p> <p>25 The -- I forget the rest of what your</p>	<p style="text-align: right;">Page 296</p> <p>1 incorrect with that. We had our facts right, our</p> <p>2 conclusion wrong.</p> <p>3 Q. You wrote that the facial slings using</p> <p>4 harvested autologous fascia which increases</p> <p>5 operative time and patient morbidity.</p> <p>6 And that's true as of today; correct?</p> <p>7 A. I would not disagree with that.</p> <p>8 Q. And you report other studies have</p> <p>9 shown a decrease in tensile strength of cadaveric</p> <p>10 fascia; correct?</p> <p>11 A. Correct. But the issue was -- we</p> <p>12 assumed at that point in time that increasing</p> <p>13 tensile strength was a good thing. We're now</p> <p>14 realizing that the pelvis and the vagina are</p> <p>15 elastic and have to bend, and so we're not</p> <p>16 necessarily agreeing with the conclusions I had in</p> <p>17 this study.</p> <p>18 Q. You found that the xenograft and</p> <p>19 cadaveric products demonstrated high degrees of</p> <p>20 inflammatory infiltrate; correct?</p> <p>21 A. That is correct. Specifically with</p> <p>22 the SIS. And those had a significant immune</p> <p>23 response to it. Yes. And those are not used in</p> <p>24 our practice at all anymore because of that.</p> <p>25 Q. Okay. What is the significance of the</p>
<p style="text-align: right;">Page 295</p> <p>1 statements were. But the --</p> <p>2 Q. Cadaveric. With regard to the</p> <p>3 cadaveric.</p> <p>4 A. And the cadaveric -- there's multiple</p> <p>5 different types of cadaveric and how they are</p> <p>6 processed. And some are good and some are not</p> <p>7 good. The one we found here raised questionable</p> <p>8 results.</p> <p>9 Q. How do you know which ones are good</p> <p>10 and not good until you try them?</p> <p>11 A. That's a major problem, but pretty</p> <p>12 much agreed upon, freeze dried irradiated cadaverics</p> <p>13 have a higher -- not degradation. Decomposition.</p> <p>14 De --</p> <p>15 Q. The irradiation process that you need</p> <p>16 to do to cadaveric tissue to reduce any potential</p> <p>17 transmission of disease is known to cause those</p> <p>18 materials to degrade; correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you wrote here that the fibrosis</p> <p>21 and scarring noted with the polypropylene mesh may</p> <p>22 also contribute to a more lasting repair; correct?</p> <p>23 A. You're correct. That was at that</p> <p>24 point in time the conclusions that we reached.</p> <p>25 And we subsequently discovered that we were</p>	<p style="text-align: right;">Page 297</p> <p>1 SIS for the porcine? Is that a single incision</p> <p>2 sling?</p> <p>3 A. No. It's just like -- instead of</p> <p>4 using cadaveric tissue for the sling, we use SIS,</p> <p>5 which is pig intestine, submucosal pig intestines.</p> <p>6 There's also porcine dermis, but both of them</p> <p>7 contain porcine DNA and are not recommended to be</p> <p>8 used.</p> <p>9 Q. And you're right. "We also noted a</p> <p>10 low degree of inflammation with polypropylene mesh</p> <p>11 compared to the other materials."</p> <p>12 A. Yes. And that's a relative statement</p> <p>13 in the short-term in the rabbit model compared to</p> <p>14 the processes that we know create a significant</p> <p>15 amount of immune response because they still have</p> <p>16 porcine DNA. So there's a major foreign body</p> <p>17 reaction to that.</p> <p>18 Q. And you found that there was a low</p> <p>19 degree of inflammation with polypropylene mesh,</p> <p>20 which was similar to what was seen with the</p> <p>21 autologous fascia; correct?</p> <p>22 A. Correct. In the short-term that is</p> <p>23 correct. That's what we found.</p> <p>24 Q. And so the polypropylene mesh in your</p> <p>25 study acted most closely to the autologous fascia;</p>

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<p style="text-align: right;">Page 298</p> <p>1 correct?</p> <p>2 A. Correct. In the rabbit model, placed</p> <p>3 transabdominally, that is the conclusions we</p> <p>4 reached in 2008.</p> <p>5 Q. All right. I mean, some of the</p> <p>6 studies you cite to are in dogs and other animals</p> <p>7 that are not even in the sling application like</p> <p>8 you tried to do; right?</p> <p>9 A. I agree.</p> <p>10 Q. So are you saying that your study is</p> <p>11 not important, or that --</p> <p>12 A. No.</p> <p>13 Q. -- the findings are inaccurate?</p> <p>14 A. No. I'm saying it has to be looked at</p> <p>15 as far as -- this is looking what the rabbit model</p> <p>16 does to these various different slings in the</p> <p>17 short-term. I think they're very important</p> <p>18 findings.</p> <p>19 Q. You say, our results -- "the</p> <p>20 alternatives to biologic material, synthetics are</p> <p>21 gaining popularity. The polypropylene mesh has</p> <p>22 shown promising initial and long-term results</p> <p>23 similar to that of autologous sling material";</p> <p>24 correct?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 300</p> <p>1 Q. You say UCLA State of the Art Urology</p> <p>2 Meeting --</p> <p>3 A. Oh. Oh.</p> <p>4 Q. -- page 4.</p> <p>5 A. That's a yearly meeting that they have</p> <p>6 that Raz and other experts discuss. That was an</p> <p>7 attendance-only meeting. That's not Grand Rounds.</p> <p>8 Q. Okay. I'm sorry.</p> <p>9 A. No.</p> <p>10 Q. Were you just kind of -- were you</p> <p>11 identifying different conferences or meetings you</p> <p>12 go to typically?</p> <p>13 A. Correct. That was continuing medical</p> <p>14 education.</p> <p>15 Q. Okay.</p> <p>16 A. Where specifically UCLA is well-known</p> <p>17 for having Dr. Raz there. So there's always a</p> <p>18 strong female urology section to it. That's all</p> <p>19 that's stating.</p> <p>20 Q. Dr. Raz is one of the proponents of</p> <p>21 needle suspension procedures over the years;</p> <p>22 correct?</p> <p>23 A. Well, he used to be. He's not</p> <p>24 anymore. He doesn't do his own procedure anymore.</p> <p>25 Q. Why not?</p>
<p style="text-align: right;">Page 299</p> <p>1 Q. And then you go on to say, "Our</p> <p>2 results indicated little degree of inflammation</p> <p>3 and significant fibrosis similar to that with</p> <p>4 autologous material"; correct?</p> <p>5 A. Correct. And that is the significant</p> <p>6 finding of that, which we did not correctly</p> <p>7 interpret our results at that point in time.</p> <p>8 Q. Well, you've stated significantly that</p> <p>9 none of the material appeared grossly infected at</p> <p>10 explantation in your study either; is that right?</p> <p>11 A. That's correct. In the rabbit model</p> <p>12 placed transabdominally, that is correct.</p> <p>13 Q. All right. I think in your report</p> <p>14 somewhere you mentioned -- and maybe I'm</p> <p>15 misstating this, but you were relying on -- or you</p> <p>16 found something important coming out of the UCLA</p> <p>17 Grand Rounds?</p> <p>18 A. No. No. I don't recall that.</p> <p>19 Q. Okay.</p> <p>20 A. I attended multiple UCLA meetings</p> <p>21 which involved discussions of meshes, but I think</p> <p>22 that's the only thing I could --</p> <p>23 Q. Okay.</p> <p>24 A. I don't think I ever attended what we</p> <p>25 call Grand Rounds.</p>	<p style="text-align: right;">Page 301</p> <p>1 A. Didn't work.</p> <p>2 Q. Okay. Do you have that Ford Cochrane</p> <p>3 Review you cited to in your expert report handy?</p> <p>4 I think it was one of the first exhibits we</p> <p>5 marked. Can I just turn to a page. I have a</p> <p>6 question for you.</p> <p>7 With the 2.1 percent mesh exposure</p> <p>8 rate they saw with the retropubic sling in the</p> <p>9 Ford Cochrane Review of 2015, would there be a</p> <p>10 scientifically reliable way of stating which, if</p> <p>11 any, of those exposures occurred due to the</p> <p>12 mechanically cut nature of the mesh?</p> <p>13 A. You have to look at those studies and</p> <p>14 see when they were published. If they're</p> <p>15 published prior to 2007, you could say all of them</p> <p>16 were attributed. If they're published after that</p> <p>17 we don't know, and they'd have to look at the</p> <p>18 studies, see if they break it down in mechanical</p> <p>19 versus laser.</p> <p>20 Q. Do any of the randomized control</p> <p>21 trials report that there was a sawing effect with</p> <p>22 the TVT mechanically cut mesh in the treatment of</p> <p>23 stress incontinence?</p> <p>24 A. I have not seen that in the</p> <p>25 literature. That is based upon my personal</p>

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<p>1 experience with Sparc, not the TVT, and then also</p> <p>2 internal documentation.</p> <p>3 Q. So if there was a 2.1 percent rate --</p> <p>4 if there was a 2.1 percent rate of exposure with</p> <p>5 the retropubic TVT sling -- and I want you to</p> <p>6 assume that all of those were mechanically cut,</p> <p>7 okay -- how would you scientifically, reliably</p> <p>8 ascertain which of those 21 patients' exposures</p> <p>9 were because of the mechanical cut nature of the</p> <p>10 mesh?</p> <p>11 A. Looking at this, I have no idea how</p> <p>12 many of these are TVT or not. It says retropubic</p> <p>13 slings, but that could be anything. It's not</p> <p>14 talking up-down, top-down, or anything. They're</p> <p>15 not comparing TVT right here necessarily.</p> <p>16 So based upon that, I don't know how</p> <p>17 to answer your question because I don't know what</p> <p>18 they're looking at, because they just say</p> <p>19 retropubic.</p> <p>20 Q. You didn't look and see how many of</p> <p>21 those studies were the TVT study?</p> <p>22 A. I did not look through those to find</p> <p>23 out that information, no.</p> <p>24 Q. So let me ask you this hypothetical</p> <p>25 then. If there were hypothetically 21 mesh</p>	<p>1 A. Correct.</p> <p>2 Q. That study didn't assess the TVT</p> <p>3 retropubic mid-urethral sling to treat stress</p> <p>4 incontinence; correct?</p> <p>5 A. Correct. It was TVT-Secur versus the</p> <p>6 TVTO.</p> <p>7 Q. And the TVTO, in that study, do you</p> <p>8 recall if there were any mesh exposures?</p> <p>9 A. I'd have to look at the study. I</p> <p>10 don't recall.</p> <p>11 Q. Do you know if that TVTO mesh was</p> <p>12 mechanical cut?</p> <p>13 A. The Secur was laser cut. And it was</p> <p>14 my understanding that the TVTO was mechanically</p> <p>15 cut.</p> <p>16 Q. And the TVTO mechanically cut had a</p> <p>17 lower rate of exposure than the TVT-Secur;</p> <p>18 correct?</p> <p>19 MR. CARTMELL: Tell him, if you know.</p> <p>20 A. Again, I do not know. I'd have to</p> <p>21 look at the study.</p> <p>22 Q. BY MR. SNELL: Are there any data in</p> <p>23 women on the TVT used to treat stress incontinence</p> <p>24 which report how many, if any, of those TVT</p> <p>25 mechanically cut slings have a sawing effect?</p>
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<p>1 exposures out of 1,000 TVT mechanically cut</p> <p>2 retropubic device cases, how would you -- would</p> <p>3 you be able to scientifically reliably say which</p> <p>4 of those 21 exposures were due to the mechanical</p> <p>5 cut nature of the mesh? And if so, how did you do</p> <p>6 that?</p> <p>7 A. In a retrospective fashion, you would</p> <p>8 not be able to determine that with precision. You</p> <p>9 could say it's going to be a contributing factor</p> <p>10 in certain numbers. Also contributing could be</p> <p>11 degradation, infection, subclinical infection, all</p> <p>12 those things. In a retrospective fashion, you</p> <p>13 cannot. That's why it has to be done</p> <p>14 prospectively.</p> <p>15 Q. And as you sit here today, you have</p> <p>16 never seen, in any prospective TVT retropubic</p> <p>17 study, any author attribute clinical mesh exposure</p> <p>18 due to a sawing of the mesh; correct?</p> <p>19 A. I'd only have to go off of data on</p> <p>20 TVT-Secur and TVT -- TOT, the Hinoul study, but</p> <p>21 that is not a TVT study. To the best of my</p> <p>22 knowledge, that has not been evaluated. It should</p> <p>23 have been, but it has not been evaluated.</p> <p>24 Q. The TVT-Secur, that was the laser cut</p> <p>25 mesh; correct?</p>	<p>1 A. To the best of my knowledge, in those,</p> <p>2 they did not use that specific terminology. The</p> <p>3 fraying and the sawing is more from internal</p> <p>4 documentation of complaints coming into Ethicon</p> <p>5 and their discussions about it.</p> <p>6 Q. Do any of the clinical studies on TVT</p> <p>7 used to treat stress incontinence report the mesh</p> <p>8 frame and its use in women?</p> <p>9 A. Again, just like the last answer, I am</p> <p>10 unaware of any manuscript that discusses that</p> <p>11 specific terminology. That comes from internal</p> <p>12 documentation and also comes from my experience</p> <p>13 with the TVT, which did the same thing. But I</p> <p>14 didn't write on that either.</p> <p>15 Q. Have you ever seen any scientifically</p> <p>16 reliable studies in women that document the</p> <p>17 incidents at which there is -- withdrawn.</p> <p>18 I just didn't remember the word. You</p> <p>19 used two words, and I wanted to use one of them.</p> <p>20 Have you ever seen any scientifically</p> <p>21 reliable studies in women utilizing the TVT</p> <p>22 retropubic device to treat incontinence that</p> <p>23 states the incidence of fraying of the mesh?</p> <p>24 A. Again, this is -- what I stated</p> <p>25 before. I've not seen that in the literature,</p>

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<p>1 that specific terminology used. That comes from</p> <p>2 the internal documents and complaints that came</p> <p>3 in.</p> <p>4 Q. Do you know the incidence for which</p> <p>5 fraying of TVT retropubic mesh in the treatment of</p> <p>6 stress incontinence occurs?</p> <p>7 A. We have to go to my report on page 21,</p> <p>8 where I talk about fraying --</p> <p>9 Q. Um-hum.</p> <p>10 A. -- and particle loss, and the sawing</p> <p>11 effect. And the incidence -- okay. It varies --</p> <p>12 as you go through the various sections here in the</p> <p>13 report on that.</p> <p>14 Say on page 22, testing done by</p> <p>15 Ethicon. So that after elongation, 18 percent of</p> <p>16 the weight was lost due to particle loss.</p> <p>17 Pariente says the point -- 8.5 percent of the</p> <p>18 particle loss.</p> <p>19 Q. But my question is specific to</p> <p>20 fraying. So what --</p> <p>21 A. Fraying?</p> <p>22 Q. Yes, sir. What -- I'm sorry. Yes,</p> <p>23 Doctor.</p> <p>24 What's the incidence of fraying that</p> <p>25 occurs? I didn't see that number in your report.</p>	<p>1 obstruction, and then what happened to those</p> <p>2 individuals.</p> <p>3 Q. What types of slings were those?</p> <p>4 A. Those were all types of slings.</p> <p>5 Retropubic, suprapubic, transobturator, and</p> <p>6 vaginal.</p> <p>7 Q. Were there any retropubic TVTs in that</p> <p>8 study?</p> <p>9 A. I'd have to look and see what we</p> <p>10 documented.</p> <p>11 Q. What was the main result of that</p> <p>12 study? What percent of the patients remained</p> <p>13 continent following sling release.</p> <p>14 A. Again, I'd have to look at that study,</p> <p>15 the exact numbers on it.</p> <p>16 Q. Do you have it with you?</p> <p>17 A. Yes, I do. I should. Actually I</p> <p>18 don't have the paper. I would have to guess on</p> <p>19 the numbers. It was a high -- the issue was --</p> <p>20 MR. CARTMELL: Don't guess. If you</p> <p>21 know, you know.</p> <p>22 A. All I'll say is there's a high rate of</p> <p>23 reoperation once we cut the sling over time. That</p> <p>24 was the significant findings.</p> <p>25 Q BY MR. SNELL: What do you mean by</p>
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<p>1 A. I don't think I state a specific</p> <p>2 number in there. However, during the placement of</p> <p>3 it, where, you know, they talk about 50 percent of</p> <p>4 these devices are elongated during the</p> <p>5 implantation with 12 pounds of force, that causes</p> <p>6 the -- to rope, fray, and particle loss. So I</p> <p>7 can't give you an exact percentage. But it is a</p> <p>8 constellation of problems that happen with that.</p> <p>9 Q. Other than your paper on the use of</p> <p>10 the Holmium laser, have you published on treating</p> <p>11 any mesh complications?</p> <p>12 A. Yes.</p> <p>13 Q. Where? What paper would that be? For</p> <p>14 stress urinary incontinence?</p> <p>15 A. Stress urinary incontinence.</p> <p>16 Q. Yes.</p> <p>17 A. I have the copy of my CV, which is an</p> <p>18 exact copy of yours.</p> <p>19 My page 17 of 25, I have the Holmium</p> <p>20 laser complication, as you mentioned. And then</p> <p>21 number 9 on this is Clifton, et al., where I'm the</p> <p>22 senior author, of Repeat Anti-Incontinence</p> <p>23 Procedures Following a Sling Release.</p> <p>24 So that's a study of individuals who</p> <p>25 had obstruction following a sling. We treated the</p>	<p>1 that?</p> <p>2 A. What I mean is the traditional thought</p> <p>3 was, based upon a Webster paper, George Webster</p> <p>4 out of Duke, is that if you cut slings, 85 percent</p> <p>5 of people stayed dry. But the problem is no one</p> <p>6 had followed those individuals long-term. So we</p> <p>7 followed them long-term and found out that over</p> <p>8 time the rate of incontinence increased, requiring</p> <p>9 further treatment. So bottom line, it's not like</p> <p>10 if you obstruct somebody, you treat it, they're</p> <p>11 done. They're great. No, they have problems</p> <p>12 later.</p> <p>13 Q. What was the mean time for your</p> <p>14 surgery to release the sling?</p> <p>15 A. I'd have to look at the paper.</p> <p>16 Q. Was it more than a year or less than a</p> <p>17 year?</p> <p>18 A. I'd have to look at the paper. I</p> <p>19 don't recall and I don't, for some reason, have a</p> <p>20 copy of it here.</p> <p>21 Q. What was the long-term follow-up that</p> <p>22 you say that you all conducted? How long was</p> <p>23 that?</p> <p>24 A. Again, that's what I'm saying. I need</p> <p>25 to see the paper because I can't recall what the</p>

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<p style="text-align: right;">Page 310</p> <p>1 duration was.</p> <p>2 Q. As you sit here today, do you know</p> <p>3 whether 50 percent or more -- strike that.</p> <p>4 As sit here today, was it more likely</p> <p>5 than not that those papers who had a sling release</p> <p>6 would not require reoperation for incontinence?</p> <p>7 A. I'll get the paper.</p> <p>8 Q. Okay.</p> <p>9 A. Because I can't recall.</p> <p>10 Q. That's fine. I don't think I have it.</p> <p>11 So if you don't remember, that's fine.</p> <p>12 MR. CARTMELL: You don't need to get</p> <p>13 the paper.</p> <p>14 MR. SNELL: It would be good if he got</p> <p>15 the paper. But that's fine. If he doesn't</p> <p>16 remember his own data, that's fine. I'm not</p> <p>17 trying to trick him. I just want to know.</p> <p>18 MR. CARTMELL: I mean, if you don't</p> <p>19 know the answer, then say you don't know, okay.</p> <p>20 A. I don't know the exact number. We</p> <p>21 worked hard on it, and to do it justice, I'd have</p> <p>22 to find the paper.</p> <p>23 Q BY MR. SNELL: Fair enough.</p> <p>24 In your Holmium laser paper, the</p> <p>25 majority of women got better; right?</p>	<p style="text-align: right;">Page 312</p> <p>1 off the record while he reviews it.</p> <p>2 MR. SNELL: It's his own paper. So</p> <p>3 you're going to waste my -- you're going to burn</p> <p>4 my time with him looking at his own paper?</p> <p>5 MR. CARTMELL: You wanted him to look</p> <p>6 at it. This is your time, period.</p> <p>7 Q. BY MR. SNELL: Okay. Doctor, could</p> <p>8 you quickly look at your own paper that you wrote?</p> <p>9 A. 14 percent of patients after a sling</p> <p>10 release ultimately went on to a repeat operation.</p> <p>11 That's what we had in our data.</p> <p>12 Q. All right. So that means 86 percent</p> <p>13 of those patients did not go on to a repeat sling</p> <p>14 operation?</p> <p>15 A. Yes. But some of those elected not to</p> <p>16 because they were scared from previous surgeries.</p> <p>17 Q. What percentage of the patients</p> <p>18 elected not to?</p> <p>19 A. I'd have to look at the study. I</p> <p>20 don't have that. So I mean, that's -- again, I'd</p> <p>21 have to look at the study.</p> <p>22 Q. Fair enough.</p> <p>23 When you do your autologous fascial</p> <p>24 slings, and the transobturator autologous slings,</p> <p>25 how do you tension those slings?</p>
<p style="text-align: right;">Page 311</p> <p>1 A. At this point. But we are still</p> <p>2 continuing to follow those, and that's what was</p> <p>3 raised in the SUFU lecture when I talked about</p> <p>4 this. We don't know what's going to happen to</p> <p>5 these people long-term.</p> <p>6 Q. Here, I have your paper. We have it</p> <p>7 here. Clifton, you said?</p> <p>8 A. Clifton.</p> <p>9 Q. This says median follow-up after</p> <p>10 release was 32 months. Of the 93 patients,</p> <p>11 14 percent required repeat anti-incontinence</p> <p>12 procedure after sling realize.</p> <p>13 A. Okay. All right.</p> <p>14 Q. That's your paper; right?</p> <p>15 A. I can't see the top of it. I'll</p> <p>16 assume you're telling me the truth, though.</p> <p>17 That's it. Yes.</p> <p>18 Q. All right. So actually, your data</p> <p>19 were consistent with other data in the literature,</p> <p>20 because 86 percent of your patients didn't require</p> <p>21 repeat anti-incontinence procedure; right?</p> <p>22 A. I'll have to see the paper.</p> <p>23 MR. SNELL: We can go off the record</p> <p>24 while he reviews that.</p> <p>25 MR. CARTMELL: No. We're not going</p>	<p style="text-align: right;">Page 313</p> <p>1 A. How do I tension them? I -- well, you</p> <p>2 said two different things. Pubovaginal or</p> <p>3 autologous transobturator. Which one?</p> <p>4 Q. Either one. Or if there's a</p> <p>5 difference, just tell me there's a difference.</p> <p>6 A. Well, there's a difference between the</p> <p>7 two.</p> <p>8 Q. Fair enough. How do you tension</p> <p>9 autologous fascial slings?</p> <p>10 A. Well, again, there's two different</p> <p>11 types. Pubovaginal or transobturator?</p> <p>12 Q. Pubovaginal?</p> <p>13 A. Pubovaginal, there's three steps to do</p> <p>14 this. Place a cystoscope in the urethra, deflect</p> <p>15 it 15 degrees. Up top in the abdomen, you tie</p> <p>16 initial knot that you can fit two finger breadths</p> <p>17 in it. Secure it with a clamp. Tie multiple</p> <p>18 knots. In doing that, you're fairly reproducible</p> <p>19 as far as the tension goes.</p> <p>20 Q. Some surgeons use one finger breadth;</p> <p>21 correct?</p> <p>22 A. It's -- you can -- yeah. Well, I</p> <p>23 can't speak to that. I do two finger breadths and</p> <p>24 it works.</p> <p>25 Q. Is that because that's how you were</p>

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<p style="text-align: right;">Page 314</p> <p>1 taught to do that procedure?</p> <p>2 A. Yeah, but I'm going to modify it.</p> <p>3 That's originally how -- oh, I was taught the</p> <p>4 leave a gap. The key is you leave it loose.</p> <p>5 Q. Okay.</p> <p>6 A. And so if you use one finger breadth</p> <p>7 or two finger breadths might not make all that</p> <p>8 difference because it's the distance from the</p> <p>9 fascia to your knot, not necessarily the width.</p> <p>10 So one finger breadth and two finger breadths is</p> <p>11 actually going to be the same.</p> <p>12 Q. You don't really use any objective</p> <p>13 measurement to assess tension; correct?</p> <p>14 A. That is an objective. 15 degrees and</p> <p>15 one finger breadth. So I have objective,</p> <p>16 reproducible data. And I have never had, in my</p> <p>17 pubovaginal slings, a patient go into retention</p> <p>18 that was not a purposeful retention.</p> <p>19 Q. You don't use any type of gauge to</p> <p>20 assess tension on the sutures; correct?</p> <p>21 A. That does not exist for the</p> <p>22 pubovaginal slings.</p> <p>23 Q. All right. And is there any</p> <p>24 literature that reports on the effect, if any, of</p> <p>25 using one, two, or three suture finger breadths of</p>	<p style="text-align: right;">Page 316</p> <p>1 reproducible in my hands.</p> <p>2 Q. Right. But you don't do all the sling</p> <p>3 surgeries in this country. So I'm more interested</p> <p>4 in out in the masses in the United States.</p> <p>5 There is a fairly high rate of urinary</p> <p>6 retention following the autologous pubovaginal</p> <p>7 sling; right?</p> <p>8 MR. CARTMELL: Object and move to</p> <p>9 strike the statement of counsel. Object to the</p> <p>10 form as well.</p> <p>11 MR. SNELL: I'll withdraw the</p> <p>12 statement.</p> <p>13 Q BY MR. SNELL: Let me just -- looking</p> <p>14 broadly, nationally, okay, across the data, there</p> <p>15 is a fairly high rate of urinary retention</p> <p>16 following autologous pubovaginal slings; correct?</p> <p>17 MR. CARTMELL: Object to the form.</p> <p>18 A. I can't agree with that. You say</p> <p>19 fairly high. I don't know that. I've not seen</p> <p>20 that data.</p> <p>21 Q BY MR. SNELL: You've seen reports in</p> <p>22 the data of rates of retention higher than</p> <p>23 20 percent following autologous pubovaginal sling?</p> <p>24 A. It depends on how you're describing</p> <p>25 retention. If you're talking immediately</p>
<p style="text-align: right;">Page 315</p> <p>1 detensioning for the autologous pubovaginal sling</p> <p>2 as opposed to some other method of tensioning?</p> <p>3 A. No, there's nothing in the literature</p> <p>4 like that. The teaching is to leave it loose.</p> <p>5 Q. And realizing you don't really do the</p> <p>6 Burch. Do you even remember how you were taught</p> <p>7 to tension or detension a Burch?</p> <p>8 A. No, I don't remember that.</p> <p>9 Q. What is wrong with the tensioning of</p> <p>10 the TVT retropubic device, if anything, in your</p> <p>11 opinion?</p> <p>12 A. It's not reproducible. The</p> <p>13 pubovaginal sling, I can tell somebody exactly</p> <p>14 like I told you. Cystoscope in, deflect it</p> <p>15 15 degrees, two finger breadths up, tie it loose,</p> <p>16 and you won't have retention.</p> <p>17 TVT, it says tension free, but then</p> <p>18 there's tension. And so it's not reproducible. I</p> <p>19 can't tell you how to tension it correctly. I can</p> <p>20 tell you the pubovaginal sling.</p> <p>21 Q. Well, with the pubovaginal sling,</p> <p>22 there is a fair number of patients who have</p> <p>23 urinary retention after that procedure; right?</p> <p>24 A. I can't speak to those. I can speak</p> <p>25 to my own experience. Like I say, it's</p>	<p style="text-align: right;">Page 317</p> <p>1 postoperatively, yes, that is very commonly.</p> <p>2 That's why a suprapubic tube or intermittent</p> <p>3 catheterization is not uncommonly required.</p> <p>4 Permanent retention after a month or six weeks,</p> <p>5 that's debatable, the duration, should be very</p> <p>6 low. In experienced people's hands, it's</p> <p>7 essentially zero. Again, my hands zero.</p> <p>8 Q. You've read the sister study by the --</p> <p>9 that was funded by the NIH that compared the</p> <p>10 autologous pubovaginal fascial sling to the Burch</p> <p>11 colposuspension, and they found statistically</p> <p>12 significant higher rates of not only voiding</p> <p>13 dysfunction and retention but retention requiring</p> <p>14 reoperation in the autologous sling arms; correct?</p> <p>15 A. That's been a long time since I've</p> <p>16 read it. I have to look at that paper. That was</p> <p>17 a good paper, but it's been a long time since I've</p> <p>18 seen it.</p> <p>19 MR. CARTMELL: I don't mean to</p> <p>20 interrupt, but I'd like to check the time, please.</p> <p>21 THE REPORTER: 7 hours and 13 minutes.</p> <p>22 MR. CARTMELL: Okay. You're done. If</p> <p>23 you want to go -- I may have a few questions. But</p> <p>24 if -- if -- we can go off the record if you want</p> <p>25 and talk about what you and Ben agreed to. It's</p>

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<p>1 just nobody told me that, and I really need to be 2 somewhere. 3 But let's go off the record right now. 4 MR. SNELL: Well, no. This needs to 5 be put on the record, and I have emails 6 documenting this, where Ben said, Burt, the MDL 7 design defect dep and New Jersey general TVT dep 8 have to done in one sitting on one day; you got to 9 do it today. And I said, okay, Ben, I will. And 10 then he and Judy Walberger, are doing the case 11 specific Watkins deposition next weekend. So that 12 was the agreement. 13 And I emailed Ben, fine, I'll do that. 14 No problem. I'll start the New Jersey general TVT 15 dep after this deposition, okay. And nobody ever 16 said that that wasn't going to occur. And I came 17 here with that expectation. And I wouldn't lie to 18 you. I mean, you've seen the email. Were you on 19 the email? It's in the email. 20 MR. CARTMELL: You don't have to 21 answer that. 22 MR. SNELL: You don't have to answer. 23 You're not under oath. 24 But with that said, what do you want 25 to do? I understand you have to do something with</p>	<p>1 idea. 2 MR. SNELL: Okay. Yeah, I mean, that 3 wasn't my idea, okay. One. 4 Two, I understand. I know -- you 5 know, look, I have a family, too, and I sympathize 6 for you. 7 But, three, I came here with that 8 intention and am ready to go. 9 And four, in New Jersey, my experts 10 have been deposed for pretty much more than 11 12 hours in a sitting. 12 (Recessed from 5:33 p.m. to 13 5:42 p.m.) 14 MR. SNELL: So I will pass the witness 15 in the MDL design defect case, and I reserve the 16 right to do the New Jersey TVT general deposition, 17 as I told Ben. 18 And I'm looking at my email that I 19 sent to him, where I said, "That's fine. I will 20 do my MDL design defect deposition first. And 21 after that we will do the New Jersey general TVT 22 deposition for anything that was not already 23 addressed." 24 I'll stand by that statement I sent to 25 Ben. I will not be duplicative. I really only</p>
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<p>1 your family. 2 MR. CARTMELL: We've been here nine 3 hours, and I don't want to put him through -- if 4 you told me you had 30 minutes or an hour, then 5 maybe, but I mean -- 6 MR. ROSENBLATT: Did they agree to 7 extend any deadline? Will that work? 8 MR. CARTMELL: What's the deadline in 9 New Jersey we're talking about? 10 MR. SNELL: I don't know. I think 11 it's October 5th or something. 12 MR. ROSENBLATT: I don't know. 13 MR. CARTMELL: Let me make a call, 14 okay. 15 MR. SNELL: Yeah. 16 MR. CARTMELL: I mean, I don't want to 17 get anybody in trouble and all that, and I get the 18 idea of having -- you know, doing them all at 19 once. But I'm telling you, I knew nothing about 20 this. And I think the idea of making a 21 deposition -- you know, he's been here 9 hours. 22 We've been on the record over 7 hours. That's 23 hard. I don't know that I want him to continue 24 this. 25 MR. ROSENBLATT: It wasn't Burt's</p>	<p>1 have the warning stuff from my quick review of his 2 report left over. So I am not foregoing my right 3 to do that portion. And I will make a statement 4 on the record that New Jersey, the deposition of 5 an expert is not limited to 7 hours. My experts 6 have been deposed in cases in New Jersey for well 7 over 10 hours. But so that's my position. And 8 I -- go ahead, Tom. 9 MR. CARTMELL: Okay. Just so it's 10 clear. We took a break. I called Ben. He told 11 me that the correspondence back and forth was -- 12 or our position, I guess, that he stated was you 13 needed to do both the New Jersey and the MDL 14 deposition today, meaning in 7 hours, because 15 there's a 7-hour requirement from the -- I'm just 16 telling you what he said, from the MDL. And that 17 the reports are the same. The general causation 18 reports. 19 You just pointed out to me that in 20 New Jersey there are failure-to-warn opinions that 21 you have not yet been able to question the witness 22 on. And I do agree with that. You have not done 23 that. 24 You've said you wanted to continue the 25 deposition for that. I had not been told -- and</p>

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<p>1 we've been here for 9 hours. I had not been told</p> <p>2 that that was going to happen today. I actually</p> <p>3 have a prior commitment that I really need to go</p> <p>4 to, and I believe the doctor is tired as well.</p> <p>5 So I've agreed, and I think you have,</p> <p>6 too, that we would go ahead and allow you that</p> <p>7 time for the warnings opinions that you have and</p> <p>8 set it up at an additional time.</p> <p>9 MR. SNELL: And at a mutually</p> <p>10 convenient date between doctor, myself, and</p> <p>11 whoever will defend.</p> <p>12 MR. CARTMELL: That's right.</p> <p>13 MR. SNELL: And I will just state for</p> <p>14 the record, too, Ben Anderson never told me he</p> <p>15 expected me to do both in 7 hours, nor does he</p> <p>16 have a basis under the New Jersey Rules of</p> <p>17 Procedure to make such a statement. I have my</p> <p>18 email that I sent to him, and there was no reply</p> <p>19 saying, no, Burt, you're wrong.</p> <p>20 MR. CARTMELL: Okay.</p> <p>21 MR. SNELL: But we have an agreement,</p> <p>22 and I'm passing the witness. Let's get this</p> <p>23 design defect deposition in the books.</p> <p>24 MR. CARTMELL: Okay.</p> <p>25 MR. SNELL: That way you can go do</p>	<p>1 A. That based upon the medical</p> <p>2 literature, Klosterhalfen, Klinge, as stated in my</p> <p>3 report, lightweight large pore meshes have lower</p> <p>4 complication rates, and that is also including the</p> <p>5 internal Ethicon documents that state</p> <p>6 acknowledgment of that fact.</p> <p>7 Q. You mentioned, when you were</p> <p>8 questioned by Mr. Snell, that the TVT, I believe</p> <p>9 you said during the first six weeks, may result in</p> <p>10 more pain.</p> <p>11 Do you recall that?</p> <p>12 MR. SNELL: Objection. Misstates.</p> <p>13 A. I don't believe I said that. That the</p> <p>14 TVT may result in more pain? No, I didn't --</p> <p>15 Q BY MR. CARTMELL: You didn't say that?</p> <p>16 A. I didn't say that.</p> <p>17 Q. I think you were talking about</p> <p>18 perioperative pain when comparing the TVT to maybe</p> <p>19 pubovaginal slings or the Burch.</p> <p>20 A. Correct.</p> <p>21 Q. Okay. When you were talking about</p> <p>22 pain during that perioperative period or during</p> <p>23 the first six weeks, what type of pain were you</p> <p>24 talking about?</p> <p>25 A. I'm talking about incisional pain,</p>
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<p>1 your thing.</p> <p>2 MR. CARTMELL: Doctor, I just have a</p> <p>3 few follow-up questions.</p> <p>4 You recall that you were asked</p> <p>5 previously about --</p> <p>6 MR. SNELL: Can you give me one</p> <p>7 second, Tom. I'm essentially sorry to interrupt</p> <p>8 you. I just have to get something to write with.</p> <p>9 Very, very sorry. Go ahead. I'll shut up.</p> <p>10 EXAMINATION</p> <p>11 BY MR. CARTMELL:</p> <p>12 Q. Do you recall being asked questions by</p> <p>13 Mr. Snell about large pore lightweight mesh?</p> <p>14 A. Yes.</p> <p>15 Q. And do you have an opinion within a</p> <p>16 reasonable degree of medical certainty that</p> <p>17 lightweight large pore mesh would lead to less</p> <p>18 complications in the TVT or in a mid-urethral</p> <p>19 sling than the TVT heavy weight small pore mesh?</p> <p>20 A. Yes.</p> <p>21 MR. SNELL: Objection. Leading. Go</p> <p>22 ahead.</p> <p>23 A. Yes.</p> <p>24 Q BY MR. CARTMELL: And what is your</p> <p>25 opinion?</p>	<p>1 pain in the suprapubic region, where the tissue</p> <p>2 may have been harvested. I'm not talking about</p> <p>3 vaginal discomfort. That would be equal. We're</p> <p>4 just giving the harvest area.</p> <p>5 Q. Are you talking about dyspareunia?</p> <p>6 A. No. I'm talking specifically</p> <p>7 perioperative incisional pain.</p> <p>8 Q. Do you have an opinion within a</p> <p>9 reasonable degree of medical certainty whether or</p> <p>10 not TVT, when compared to pubovaginal slings or</p> <p>11 Burch slings, causes more dyspareunia or vaginal</p> <p>12 pain on a long-term basis?</p> <p>13 MR. SNELL: Objection. Beyond the</p> <p>14 scope. Non-disclosed opinion in the report.</p> <p>15 Go ahead.</p> <p>16 A. Based upon my clinical experience, my</p> <p>17 discussion with colleagues, review of the</p> <p>18 literature, and what is outlined in my expert</p> <p>19 report, TVT, in the long-term, causes increased</p> <p>20 risk for dyspareunia and the severity of that</p> <p>21 dyspareunia.</p> <p>22 Q BY MR. CARTMELL: What about with</p> <p>23 vaginal pain?</p> <p>24 A. Vaginal pain would be the --</p> <p>25 MR. SNELL: Same objection. Go ahead.</p>

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<p>1 Doctor. I'm sorry.</p> <p>2 A. They would be the same. Vaginal pain</p> <p>3 implies a constant vaginal pain. Dyspareunia is</p> <p>4 just during sexual activity. And, yes, in my</p> <p>5 experience, I do not see pubovaginals and Burchs</p> <p>6 come in with that type of pain. On a daily basis,</p> <p>7 I see the TVT that way.</p> <p>8 MR. CARTMELL: Okay. That's all I</p> <p>9 have.</p> <p>10 MR. SNELL: A couple of quick</p> <p>11 questions in follow-up.</p> <p>12 EXAMINATION</p> <p>13 BY MR. SNELL:</p> <p>14 Q. Cobb, Klosterhalfen and Klinge, none</p> <p>15 of those are pelvic surgeons; correct?</p> <p>16 A. Clave, I don't know what he is. The</p> <p>17 first two, Klinge and Klosterhalfen are</p> <p>18 pathologists, I believe.</p> <p>19 Q. Cobb is not --</p> <p>20 A. Cobb is not. And I don't know if I</p> <p>21 mentioned it. I mentioned -- Clave should be on</p> <p>22 there, and I believe he is a pelvic surgeon, but I</p> <p>23 don't know his specific credentials.</p> <p>24 Q. But Cobb, Klosterhalfen, Klinge, none</p> <p>25 of them published on the TVT device assessed in</p>	<p>1 pain from either of those aforementioned</p> <p>2 procedures. But I see it commonly, weekly with</p> <p>3 the meshes, including the TVT.</p> <p>4 Q. You can't point to any comparative</p> <p>5 trials that show a statistically significantly</p> <p>6 higher rate of dyspareunia for the TVT retropubic</p> <p>7 device compared to either the Burch or the</p> <p>8 pubovaginal sling; correct?</p> <p>9 A. Those studies, as you've mentioned,</p> <p>10 have not been done.</p> <p>11 Q. And actually, the one paper you</p> <p>12 pointed me to earlier about the Burch had the</p> <p>13 4 percent rate of dyspareunia with that procedure</p> <p>14 long-term; correct?</p> <p>15 A. It wasn't 4 percent. It was</p> <p>16 3.9 percent.</p> <p>17 Q. So -- okay. If you round up, it's</p> <p>18 4 percent; correct?</p> <p>19 A. I don't round up, though.</p> <p>20 Q. Okay. And you can't point to any</p> <p>21 studies on TVT that show a rate higher than</p> <p>22 3.9 percent at that length of follow-up for</p> <p>23 dyspareunia; can you?</p> <p>24 MR. CARTMELL: Object to the form.</p> <p>25 A. Because that study has not been done.</p>
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<p>1 women; correct?</p> <p>2 A. That is correct, yes.</p> <p>3 Q. Just so we're clear on the record, the</p> <p>4 increased perioperative incisional pain that you</p> <p>5 just talked to Mr. Cartmell about, that actually</p> <p>6 occurs in the autologous pubovaginal arm; is that</p> <p>7 correct?</p> <p>8 A. That is correct. It would be fair to</p> <p>9 say that, in my experience, the immediate</p> <p>10 perioperative period, you will have an increased</p> <p>11 incisional pain that is still treated with</p> <p>12 medications and tolerable, but it will be more</p> <p>13 than the TVT.</p> <p>14 Q. Now, I believe you said that you</p> <p>15 believe that the long-term dyspareunia rates with</p> <p>16 the TVT were higher than pubovaginal, did you say,</p> <p>17 and the Burch?</p> <p>18 A. I don't recall if I mentioned the</p> <p>19 Burch in there.</p> <p>20 What I mentioned was the pubovaginal</p> <p>21 and the Burch have traditionally been a very</p> <p>22 common procedure done up until the mid-'90s and</p> <p>23 into probably early 2000's.</p> <p>24 And in my practice, I have never seen</p> <p>25 a woman come in with severe pain, life altering</p>	<p>1 As I mentioned, no studies focused specifically on</p> <p>2 output -- end point of dyspareunia have been done.</p> <p>3 Q BY MR. CARTMELL: So the answer to my</p> <p>4 question is, yes, you can't point to that study;</p> <p>5 correct?</p> <p>6 MR. CARTMELL: Object to the form.</p> <p>7 Asked and answered.</p> <p>8 A. That's what I mentioned. Those</p> <p>9 studies with that specific end point have not been</p> <p>10 done.</p> <p>11 Q BY MR. CARTMELL: Except you know that</p> <p>12 there's a 10-year TVT retropubic study, lead</p> <p>13 author Heinonen, that reports zero cases of</p> <p>14 dyspareunia at 10 years follow-up.</p> <p>15 Did you know that?</p> <p>16 A. You would have to show me that study.</p> <p>17 Q. Do you know that study?</p> <p>18 A. I'm saying, you'd have to show me that</p> <p>19 study. I've read a lot of studies. I can't</p> <p>20 recall that one specifically. So I'd have to look</p> <p>21 at that.</p> <p>22 Q. So you very well may be wrong when you</p> <p>23 make statements like there's no long-term studies</p> <p>24 that look at TVT and dyspareunia?</p> <p>25 MR. CARTMELL: Object to the form.</p>

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<p style="text-align: right;">Page 330</p> <p>1 Q. BY MR. SNELL: Correct?</p> <p>2 A. Also certain studies I've looked at, I</p> <p>3 disregard --</p> <p>4 Q. Can you say yes or no?</p> <p>5 MR. CARTMELL: Let him answer the</p> <p>6 question?</p> <p>7 A. That's not a yes or no. It's more</p> <p>8 complicated than that. I review a lot of studies.</p> <p>9 Some of them get disregarded because they're so</p> <p>10 poor quality that they're not worth quoting. So</p> <p>11 that particular study I'd like to see and we can</p> <p>12 dissect that one out.</p> <p>13 Q. And if I'm correct --</p> <p>14 MR. CARTMELL: You said a couple. So</p> <p>15 you went over 7 hours. And I'm here for the MDL</p> <p>16 portion.</p> <p>17 MR. SNELL: I didn't go over 7 hours.</p> <p>18 MR. CARTMELL: You went 7 hours and 13</p> <p>19 minutes.</p> <p>20 MR. SNELL: No, no. That was 6 hours;</p> <p>21 wasn't it?</p> <p>22 MR. CARTMELL: No. It was 7 hours and</p> <p>23 13 minutes. I let you ask a few. We done.</p> <p>24 MR. SNELL: Okay.</p> <p>25 MR. CARTMELL: And you could have</p>	<p style="text-align: right;">Page 332</p> <p>1 compared to the mid-urethral sling; correct?</p> <p>2 A. I'd have to look at that. That's a</p> <p>3 799-page document. I'd have to see that.</p> <p>4 Q. As you sit here today, you can't</p> <p>5 answer my question?</p> <p>6 A. Oh, I can answer. Let's pull out the</p> <p>7 document, take a look at it.</p> <p>8 Q BY MR. SNELL: Do you want to do that?</p> <p>9 MR. CARTMELL: I mean, I'm not giving</p> <p>10 you any more time. So you don't have the time to</p> <p>11 do that. This whole day you've been asking him</p> <p>12 questions about things and you've been making</p> <p>13 statements from those documents without showing</p> <p>14 them to him.</p> <p>15 MR. SNELL: No, no. He's got these</p> <p>16 documents.</p> <p>17 MR. CARTMELL: No, no.</p> <p>18 MR. SNELL: I wouldn't misrepresent.</p> <p>19 MR. CARTMELL: All day long.</p> <p>20 MR. SNELL: Do you want me to show him</p> <p>21 the numbers? You know the numbers. I used them</p> <p>22 with Dr. Rosenswath.</p> <p>23 MR. CARTMELL: No. I want to be done.</p> <p>24 You're over your 7 hours. So let's go.</p> <p>25 Q BY MR. SNELL: As you sit here,</p>
<p style="text-align: right;">Page 331</p> <p>1 saved your time.</p> <p>2 MR. SNELL: Well, I have two more</p> <p>3 considering you've asked him to comment and say</p> <p>4 rates are higher. That's not even in his expert</p> <p>5 report, okay. He doesn't put in his expert report</p> <p>6 what the rates are for Burch, for the pubovaginal,</p> <p>7 or the TVT.</p> <p>8 MR. CARTMELL: I didn't ask him what</p> <p>9 the rates were.</p> <p>10 MR. SNELL: Yes, you did.</p> <p>11 MR. CARTMELL: No, I didn't. I</p> <p>12 said --</p> <p>13 MR. SNELL: You said higher.</p> <p>14 MR. CARTMELL: -- the claim is it's</p> <p>15 higher, and it says that in his expert report.</p> <p>16 MR. SNELL: No, it doesn't.</p> <p>17 MR. CARTMELL: Yes, it does.</p> <p>18 MR. SNELL: It can't be higher. He</p> <p>19 doesn't even have the rates.</p> <p>20 Q BY MR. SNELL: How about this? You've</p> <p>21 seen the AUA guideline from 2012 and the SGS</p> <p>22 systematic meta-analysis and review, and in both</p> <p>23 of those systematic reviews, they report higher</p> <p>24 rates of dyspareunia, pain, and sexual dysfunction</p> <p>25 with the autologous sling and the Burch as</p>	<p style="text-align: right;">Page 333</p> <p>1 Doctor, can you answer my question without me</p> <p>2 showing you those papers?</p> <p>3 A. I want to see those papers.</p> <p>4 MR. CARTMELL: No.</p> <p>5 MR. SNELL: Fair enough.</p> <p>6 MR. CARTMELL: The question was: Can</p> <p>7 you answer it without seeing the papers. If you</p> <p>8 can't answer it without seeing it, just say no.</p> <p>9 A. I cannot answer it without it. It's a</p> <p>10 799-page document. I would need to see those</p> <p>11 papers.</p> <p>12 MR. SNELL: Fair enough.</p> <p>13 MR. CARTMELL: Go ahead. Thank you</p> <p>14 very much.</p> <p>15 (Deposition concluded at 5:54 p.m.)</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>

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<p>1 REPORTER'S CERTIFICATE</p> <p>2</p> <p>3 I, NAOLA C. VAUGHN, a Certified Court</p> <p>4 Reporter within and for the States of Missouri and</p> <p>5 Kansas, hereby certify that the within-named witness</p> <p>6 was first duly sworn by me to testify to the truth;</p> <p>7 and that the deposition by said witness was given in</p> <p>8 response to the questions propounded, as herein set</p> <p>9 forth; was first taken in machine shorthand by me</p> <p>10 and afterwards reduced to writing under my direction</p> <p>11 and supervision; and is a true and correct record of</p> <p>12 the testimony given by the witness.</p> <p>13 I further certify that I am not a relative</p> <p>14 or employee or attorney or counsel of any of the</p> <p>15 parties, or a relative or employee of such attorneys</p> <p>16 or counsel, or financially interested in the action.</p> <p>17 WITNESS my hand and official seal at</p> <p>18 Tonganoxie, Kansas, this 29th day of September 2015.</p> <p>19</p> <p>20</p> <p>21</p> <p>22 NAOLA C. VAUGHN, CCR, CRR, RPR</p> <p>23 Missouri CCR No. 1052</p> <p>24 Kansas CCR No. 0895</p> <p>25</p>	<p>1 -----</p> <p>2 E R R A T A</p> <p>3 -----</p> <p>4 PAGE LINE CHANGE</p> <p>5 REASON: _____</p> <p>6 REASON: _____</p> <p>7 REASON: _____</p> <p>8 REASON: _____</p> <p>9 REASON: _____</p> <p>10 REASON: _____</p> <p>11 REASON: _____</p> <p>12 REASON: _____</p> <p>13 REASON: _____</p> <p>14 REASON: _____</p> <p>15 REASON: _____</p> <p>16 REASON: _____</p> <p>17 REASON: _____</p> <p>18 REASON: _____</p> <p>19 REASON: _____</p> <p>20 REASON: _____</p> <p>21 REASON: _____</p> <p>22 REASON: _____</p> <p>23 REASON: _____</p> <p>24 REASON: _____</p> <p>25 REASON: _____</p>
<p>Page 335</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it. It will be</p> <p>10 attached to your deposition.</p> <p>11 It is imperative that you</p> <p>12 return the original errata sheet to the</p> <p>13 deposing attorney within thirty (30) days</p> <p>14 of receipt of the deposition transcript</p> <p>15 by you. If you fail to do so, the</p> <p>16 deposition transcript may be deemed to be</p> <p>17 accurate and may be used in court.</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>Page 337</p> <p>1 ACKNOWLEDGMENT OF DEPONENT</p> <p>2</p> <p>3 I, _____, do</p> <p>4 hereby certify that I have read the</p> <p>5 foregoing pages, and that the same</p> <p>6 is a correct transcription of the answers</p> <p>7 given by me to the questions therein</p> <p>8 propounded, except for the corrections or</p> <p>9 changes in form or substance, if any,</p> <p>10 noted in the attached Errata Sheet.</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15 DANIEL STEVEN ELLIOTT, M.D. DATE</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p> <p>Subscribed and sworn</p> <p>to before me this</p> <p>_____ day of _____, 20____.</p> <p>My commission expires: _____</p> <p>Notary Public</p>

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EXHIBIT I

Notice of FDA Warning regarding the use of vaginal mesh:

The U.S. Food and Drug Administration (FDA) has issued several safety communications about the use of mesh for pelvic organ prolapse (POP). However, this AUA guideline reviews the current literature regarding SUI alone, and covers neither POP nor mini-incision slings. The FDA warning does not apply to biologicals used in POP. Based on continuing adverse event reports that have been received by the FDA since their initial warning in 2008, the FDA has stated that serious complications associated with surgical mesh in transvaginal POP repairs are not rare.

The AUA will continue to monitor the FDA's alerts and notices and will update the guideline as additional warnings or alerts regarding this device are issued. Informed consent requires that patients be advised of the risks of vaginal mesh.

The FDA will provide updates on its Web page:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm>.

Guideline for the Surgical Management of Female Stress Urinary Incontinence: 2009 Update

Female Stress Urinary Incontinence Guideline Update Panel:

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**American
Urological
Association**

Education and Research, Inc.

Rodney Alan Appell, MD, FACS

1948 – 2009



Dr. Rodney Appell served as Professor of Urology and Gynecology and Chief, Division of Voiding Dysfunction and Female Urology, at Baylor College of Medicine and held a large private practice in Houston, Texas. He was a highly respected surgeon in female urology and an active member of the American Urological Association (AUA), serving on the Practice Guidelines Committee and the Special Women's Issues in Urology Committee.

At the time of his death, he was Chair of the expert Panel that developed the Stress Urinary Incontinence Clinical Guideline. Directing the Panel members through the painstaking and analytical challenge of systematically reviewing clinical studies so that appropriate practice recommendations could be made was an undertaking at which Dr. Appell excelled. In remembering him, the current guideline Chair, Roger R. Dmochowski, M.D., Professor, Dept of Urologic Surgery, Vanderbilt University, speaking for the Panel, remarked that "Rodney will be missed by us all. His vision of mentorship was the inspiration for a whole generation of residents and fellows. Those of us who knew him will treasure the memory of his unique insight and clinical expertise."

After receiving his medical degree from Jefferson Medical College, Dr. Appell completed his surgical residency at George Washington University Medical Center and residency in urology at Yale University. Since that time and until his death he achieved extensive accomplishments in his field through research, clinical practice, and education activities. Consistently included in the publication *The Best Doctors in America*, Dr. Appell published over 100 full papers or editorials in peer-reviewed journals, authored several book chapters, was invited to participate in more than 200 lectureships and symposia, and delivered over 800 educational talks and presentations both across the United States and around the world. He served on the editorial boards of many publications, including the AUA Journal of Urology. In February 2008, he was awarded the Lifetime Achievement Award by the Society for Urodynamics and Female Urology and was named Continence Care Champion by the National Association for Continence.

Dr. Appell's leadership and expertise will be missed by all who knew him. The Stress Urinary Incontinence Guidelines Panel dedicates this Clinical Guideline to his memory.

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Introduction

Stress urinary incontinence (SUI) has a significant impact on the quality of life for many women, although estimates of prevalence vary widely due to inconsistencies in the definitions of SUI and differences in populations studied.¹ A large meta-analysis reported an estimated prevalence for urinary incontinence of 30% in women aged 30 to 60 years, with approximately half of the cases attributed to SUI;² another study reported the prevalence of SUI was 5% to 30% in European women.³ Many women in the United States (U.S.) elect to have a surgical procedure for management of their SUI symptoms each year. The first Female Stress Urinary Incontinence Clinical Guidelines Panel reviewed literature available up to January 1994 and published its report in 1997.⁴ Since that time, a new body of literature has emerged on primarily novel surgical interventions for the treatment of SUI. For these reasons, the American Urological Association (AUA) has elected to update the initial report on the Surgical Management of Stress Urinary Incontinence. The literature search used in this analysis had a conclusion date of June 2005; it is recognized that this guideline will likely change in response to new information and further developments in the field.

In the 1997 guideline, the index patient was an otherwise healthy female patient with SUI without significant pelvic organ prolapse. It has become apparent since the prior guideline that many women with SUI also have pelvic organ prolapse and that these two issues may be addressed concurrently. Therefore, in constructing this guideline update, the index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and prolapse who elects to have treatment of her

SUI along with surgical correction of prolapse. The current Female Stress Urinary Incontinence Guideline Update Panel (the Panel) was selected by the Panel chair and approved by the Practice Guidelines Committee (PGC) of the AUA. The Panel members are representative of different medical specialties and geographic regions of the U.S. and are from both academic and private institutions.

This report describes an analysis of efficacy and safety outcomes for surgical procedures for use in treatment of SUI and provides a guideline based on review of these data and/or panel consensus. It also offers a discussion about the diagnostic evaluation of the index patient and recommendations for outcomes reporting and future research.

Definitions

Stress urinary incontinence is a symptom that refers to leakage of urine during events that result in increased abdominal pressure such as sneezing, coughing, physical exercise, lifting, bending and even changing positions. There are two principle causes of this symptom – SUI and the rarer stress-induced detrusor overactivity (involuntary detrusor contractions that are caused by sudden increases in abdominal pressure). The distinction between these two can be determined by (in order of increasing specificity) patient history, physical examination (e.g., urinary loss after a stress event) and urodynamic studies. For the purposes of this guideline, it is assumed that patients in the extracted studies had surgical management of SUI.

Urgency refers to a sudden, compelling desire to pass urine which is difficult to defer⁵ or a strong need to pass urine for fear of leakage.⁶ Urge urinary incontinence is defined as

involuntary leakage accompanied by or immediately preceded by urgency.⁵ Mixed incontinence refers to SUI that occurs in combination with urge urinary incontinence.

Index patient

The index patient is defined as an otherwise healthy female patient who has elected surgical therapy for the correction of SUI as in the previous guideline. An additional index patient defined by the panel is an otherwise healthy female patient with SUI and pelvic organ prolapse who elects to have treatment of her SUI along with surgical correction of pelvic organ prolapse. Either index patient may be untreated or previously surgically-treated and may have urethral hypermobility and/or intrinsic sphincter deficiency. Urethral hypermobility was defined by the author; no uniform definition was used.

Methodology

This guideline included analysis of those relevant factors (perceived risks and outcomes of the interventions, patient preferences and relative priorities of the interventions given limited health care resources) used to choose among alternative treatment interventions.⁷ The peer-reviewed medical literature was meta-analyzed to estimate outcomes of treatment modalities, and Panel members themselves served as proxies for patients in considering preferences. The steps taken to develop this guideline, further detailed in Chapter 2, included problem definition, literature search, data extraction, systematic evidence combination, guideline generation, approval and dissemination. The Panel did not review needle suspensions or anterior colporrhaphy in

developing this guideline update. Since development of the 1997 guideline, very limited new data has been published addressing these procedures, and there is a lack of current use or interest in them as well. Though these operations may still be performed in isolated circumstances by some surgeons, the Panel believes that they are largely of historical interest only and no longer considers these procedures contemporary treatments for SUI.

Problem Definition

This guideline update was based on the original AUA Guideline on the Surgical Management of Female Stress Urinary Incontinence published in 1997 using a similar methodology. The analysis was likewise limited to surgical treatments but included new procedures and those considered the most efficacious as determined by the previous analysis. Unlike the 1997 guideline, outcomes of surgical therapies for prolapse were also included.

Surgical efficacy was defined in three parts: 1) the resolution and lack of recurrence of SUI and urgency; 2) the resolution of prolapse and the lack of recurrence or new onset of prolapse; and 3) the incidence and severity of adverse events of these treatments. Urgency (resolution and de novo) was included as an efficacy outcome due to its significant impact on patient quality of life. The treatments included in the analysis were retropubic suspensions, slings, injection therapy and artificial sphincters; the analysis excluded those procedures not generally available in the U.S. or not expected to be approved at the time of publication. Anterior repairs for prolapse reduction in conjunction with other surgical treatments for incontinence were included as prolapse surgeries. Procedures used to correct prolapse included hysterectomy in conjunction with or as a component of surgical treatment of SUI and site-specific repairs.

Literature Search and Data Extraction

A database was generated that included articles retrieved for the previous guideline and those resulting from a series of four MEDLINE® searches beginning in December 2002 and concluding in June 2005. The searches were limited to papers involving human subjects and published in the English language on or after 1990 which included the MeSH term “female.” The MeSH headings used were “urinary incontinence, stress,” “stress incontinence” and “urinary incontinence” in any field. A total of 7,111 citations and abstracts were reviewed for relevance by the panel chairs, of which 1,302 citations entered the extraction process. Panel members extracted data from the articles which were then entered into a Microsoft Access® (Microsoft, Redmond, WA) database. In person and via conference calls, the Panel collectively reviewed the extracted data. A total of 436 articles were suitable for inclusion in the meta-analysis; an additional 155 articles were deemed suitable only for their complications data due to an insufficient follow-up duration for the efficacy outcomes analysis.

Evidence Combination

To generate outcomes tables, estimates of the probabilities and/or magnitudes of the outcomes are required for each intervention. Ideally, these come from a synthesis or combination of the evidence. Combination can be performed in a variety of ways depending on the nature and quality of the evidence. For this guideline, the panel used the confidence profile method,^{8,9} which provides methods for meta-analyzing data from studies that are not randomized controlled trials (RCTs). Meta-analysis was performed using the Fast*Pro software to combine individual arms from controlled trials and clinical series where similar patients were similarly treated. Although a number of RCTs were found through the literature search, there were insufficient numbers on any one topic to warrant an independent meta-analysis of RCTs. The results of

certain trials are discussed where relevant. Frequently, published series used in a combined analysis showed very divergent results implying site-to-site variations, variability in patient populations, in the performance of the intervention, the skill of the surgeon or normal statistical variation. Given these differences, a random-effects, or hierarchical, model was used to combine the studies.

Patient Groups

While stratifying outcomes based on patient characteristics such as type of incontinence, previous treatment(s), presence of prolapse, prior pregnancy and severity of incontinence would be most instructive, in most cases the outcomes data were not fully or consistently identified by these criteria. Therefore, analysis was limited to two patient groups; one in which no patient received concomitant surgical treatment for prolapse (comparable to the previous guideline) and another in which some or all patients received concomitant treatment for prolapse. Very few published studies included all of the SUI patients receiving concomitant prolapse treatment, therefore, the analysis was based mainly on data from studies that included some patients with prolapse treatment. This did not permit a clear distinction to be made between these groups in the analysis. An attempt to stratify the outcomes of SUI surgical interventions by the presence of prolapse was thwarted by insufficient data since few published studies stratified results in this manner.

Efficacy Analysis

The efficacy outcomes analyzed included two levels of continence: cured/dry and cured/dry/improved; these are reported percentages and credible intervals (Bayesian confidence intervals [CIs]). Allocation to the previously mentioned categories was determined by author definition of continence. For the analysis of postoperative urgency, patients were divided into

three categories: without pre-existing urgency, with pre-existing urgency, and unknown or uncertain pre-existing urgency. Postoperative urgency categories included urge incontinence, urge symptoms and unspecified. Again, the results are reported as the percent of the relevant patient group having each outcome. Abbreviated tables summarizing the cured/dry and resolution or urge incontinence for the time interval of 12-23 months for patients with or without concurrent prolapse treatment are provided with this document (see Tables 1–3); for a complete set of data tables see Appendices A7-A16.

Complications

Complications were analyzed similarly to the efficacy outcomes. However, because of the wide variety of ways authors name and describe complications, the panel attempted to group complications together that represented the same or related outcomes. As discussed in Chapter 2, this could result in some inaccuracies in the resultant estimates. Appendix A-17 shows how the panel grouped outcomes. Certain complication outcomes such as pain and de novo urgency were tabulated as defined by the author, and no further analysis was performed based upon the limitations of data reporting. After grouping the complications for analysis, the grouped complications were then put into general categories for display and discussion. Outcomes tables were developed for each group of complications. Separate tables were again created for patients with and without prolapse treatment. The format of the tables is the same as the efficacy tables. An abbreviated table summarizing retention data for patients with or without concurrent prolapse treatment is provided with this document (see Table 4); for a complete set of data tables see Appendices A7 – A16.

Guideline Generation and Approvals

After the evidence was combined and outcome tables were produced, the Panel reviewed the results and identified anomalies, updated the outcomes tables based on the problems identified, and based on evidence from the outcome tables and expert opinion, the Panel drafted the treatment guideline. Based on 24 peer reviewer comments, the Panel revised the document. The guideline was submitted for approval to the PGC of the AUA and the Board of Directors for final approval.

As in the previous guideline, the present statements are graded with respect to the degree of flexibility in application. Although the terminology has changed slightly, the current three levels are essentially the same as in the previous guideline. A "standard" has the least flexibility as a treatment policy. A "recommendation" has significantly more flexibility, and an "option" is even more flexible. These terms are defined as follows:

1. **Standard:** A guideline statement is a standard if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) there is virtual unanimity about which intervention is preferred.
2. **Recommendation:** A guideline statement is a recommendation if (1) the health outcomes of the alternative interventions are sufficiently well known to permit meaningful decisions, and (2) an appreciable, but not unanimous majority agrees on which intervention is preferred.
3. **Option:** A guideline statement is an option if (1) the health outcomes of the interventions are not sufficiently well known to permit meaningful decisions, or (2) preferences are unknown or equivocal.

Dissemination

The guideline is published on the web site for the AUA and can be found at

<http://www.auanet.org>. A version of Chapter 1 will be published in the *Journal of Urology*.

Diagnostic Evaluation of the Index Patient

The purpose of diagnostic evaluation is three-fold: 1) to document and characterize SUI; 2) to assess differential diagnosis and comorbidities; and 3) to prognosticate and aid in the selection of treatment.

To confirm the diagnosis and characterize SUI

Stress urinary incontinence may be characterized by the following:

- demonstration of leakage with increasing abdominal pressure (see below)
- frequency of incontinence episodes (diagnosed by history, questionnaire, bladder diary)
- severity (the volume of urine leakage diagnosed by history, questionnaire, bladder diary, pad test)
- degree of bother (diagnosed by history, bladder diary, questionnaire)
- sphincter function (diagnosed by examination, Valsalva leak point pressure, urethral pressure profile)
- degree of urethral mobility (diagnosed by estimation at time of physical examination, cotton-swab test, or imaging)

On the basis of a focused history and physical examination with a comfortably full bladder, the diagnosis of SUI is fairly straightforward in the index patient. The *sine-qua-non* for a definitive diagnosis is for the examiner to witness involuntary urine loss from the urethral meatus

coincident with increased abdominal pressure (positive stress test) such as those occurring during coughing and straining; a standing position may facilitate the diagnosis. Once the increase in abdominal pressure has subsided, flow through the urethra should subside. Rarely, one may witness urine loss after increases in intra-abdominal pressure. In this scenario, one should suspect that the incontinence is, at least in part, due to an abnormal detrusor contraction (stress-induced detrusor overactivity).

To assess differential diagnosis and comorbidities

The differential diagnosis of stress incontinence includes detrusor overactivity, low bladder compliance, overflow incontinence, stress-induced detrusor overactivity, urethral diverticulum, urinary fistula and ectopic ureter. Overflow incontinence is a clinical diagnosis, whereas detrusor overactivity, low bladder compliance, and stress-induced detrusor overactivity are essentially urodynamic diagnoses while urethral diverticulum and urinary fistula can be sometimes be confirmed on the basis of history and exam but may in some instances require urinary tract imaging or other procedures for confirmation. Various imaging techniques for urethral diverticula may be used. Urinary fistula and ectopic ureter may be diagnosed by examination, cystoscopy and upper and lower urinary tract imaging.

Certain comorbidities relating to coexisting conditions might affect the outcome of treatment and influence surgical technique and the specifics of patient counseling. For example, a patient with mixed and stress incontinence who has a large post-void residual volume and impaired detrusor contractility might be counseled that her urge symptoms are more likely than usual to persist and that urinary retention is more likely. Further, the technique of surgery might be tailored such that a mid urethral, rather than bladder neck, sling is performed and it might be placed a bit looser than otherwise. These comorbidities include:

- urinary urgency and urge incontinence (diagnosed by history, questionnaire, bladder diary);
- anatomic features such as pelvic organ prolapse (diagnosed by history, exam); urethral mobility and other urethral abnormalities such as intrinsic stricture disease (diagnosed by cystoscopy, cotton-swab test, ultrasound);
- the number and location of ureteral orifices e.g. ectopic (diagnosed by cystoscopy); and/or
- the presence of detrusor overactivity, urethral obstruction, low bladder compliance and impaired or absent detrusor contractility (diagnosed by uroflow, postvoid residual volume determination, urodynamics).

To aid in prognosis and selection of treatment

There are few facts and many opinions about predicting the outcome of surgery based on the comorbidities described above, though few would disagree that operations for SUI should be confined to those who actually have demonstrable SUI, including occult SUI demonstrable only after reduction of pelvic organ prolapse. There is no standardized way to reduce a prolapse to unmask stress incontinence, and this patient falls outside the index patient identified by the panel. Nevertheless, an understanding of the specific comorbidities allows for individualized treatment planning, for informed consent and for the surgeon's estimate of a successful outcome and the potential occurrence of complications such as incomplete bladder emptying, persistent or de novo urgency/urge incontinence and recurrent sphincter incontinence. Urodynamic evaluation may be of assistance in elucidating complex presentations of incontinence.

Diagnostic Guidelines for the Index Patient

Amendments to 1997 Standards, Recommendations and Options are indicated (words that are in italics denote changes from the 1997 guideline document to improve clarity).

Standard: The evaluation of the index patient should include the following components:

- ***Focused* history**
- ***Focused* physical examination**
- **Objective demonstration of SUI**
- ***Assessment of postvoid residual urine volume***
- **Urinalysis, and culture if indicated**

[Based on Panel consensus]

Recommendation: Elements of the history should include the following:

- **Characterization of incontinence (stress, urge, etc.)**
- **Frequency, bother and severity of incontinence episodes**
- **Impact of symptoms on lifestyle**
- **Patient's expectations of treatment**

[Based on Panel consensus]

Recommendation: Additional diagnostic studies can be performed to assess the integrity and function of the lower urinary tract.

- **Pad testing and/or voiding diary**
- **Urodynamics**

- **Cystoscopy**
- **Imaging**

[Based on Panel consensus]

Recommendation: Indications for further testing include the following:

- **An inability to make a definitive diagnosis based on symptoms and the initial evaluation**
- **Concomitant overactive bladder symptoms**
- **Prior lower urinary tract surgery, including failed anti-incontinence procedures**
- **Known or suspected neurogenic bladder**
- **Negative stress test**
- **Abnormal urinalysis such as unexplained hematuria or pyuria**
- **Excessive residual urine volume**
- **Grade III or greater pelvic organ prolapse**
- **Any evidence for dysfunctional voiding**

[Based on Panel consensus]

The need for further evaluation of any given patient depends on a number of other factors including the degree of certainty and comfort that the physician has about the diagnosis, the impact that further studies will have on diagnosis, treatment options and treatment risks and likely outcomes as well as the desire and willingness of the patient to undergo further studies.

Therapeutic Options

Nonsurgical Treatment

Management of SUI includes the option of nonsurgical therapies. The Panel did not review nonsurgical therapies because they are outside the scope of this report.

Surgical Treatment

The outcomes analyzed fell into two general categories: efficacy outcomes and complications. The results of the analysis are provided under each treatment below. For a more detailed discussion of the outcomes, see Chapter 3. Comparative results of the meta-analysis of efficacy and complications are shown in the tables and graphs in Chapter 3.

Outcomes Analysis

Efficacy

The primary efficacy outcome was the resolution of stress incontinence as measured two ways—patients who were completely dry (cured/dry) or patients who showed improvement (cured/dry/improved). The cured/dry/improved measure may include patients who were completely dry. Secondary efficacy outcomes dealt with changes in urgency as described in the methodology section above. Data were accepted as reported except when described in terms that conflicted with the definition in the methodology. For example, if a study reported any patients with minimal persistent incontinence as cured, these data were included only in the cured/dry/improved category.

Outcomes were analyzed separately based on whether the continence evaluation was subjective or objective; only results that were clearly based on subjective or objective criteria

were included in their respective analyses. An additional category was created (defined as “any” method of evaluation) to include all studies irrespective of the method of assessment used. For studies reporting both subjective and objective results, the subjective results for the study were included in the “any” category.

Outcomes also were analyzed separately according to the postsurgical interval of the final assessment of continence, with a minimum period of follow-up of 12 months. Three intervals were analyzed: 12 to 23 months, 24 to 47 months and greater than 48 months. If a study reported data at multiple times during one of these intervals, the time point closest to 18 months, 36 months and 60 months were used for the three time ranges, respectively.

Complications

In order to facilitate the analysis of complications for the various SUI surgical procedures and because of the lack of standardized complications nomenclature in the literature the Panel grouped the reported complications into the following classes:

- Urinary retention
- Perioperative genitourinary
- Delayed genitourinary
- Gastrointestinal
- Vascular
- Neurological
- Infectious
- General medical
- Death

Details of these groups are described in Chapter 3. Appendix A-17 lists the specific complications that were included in each of the above classes. Subjective complications (pain, sexual dysfunction, and voiding dysfunction) were also included as a separate category.

Important complications for specific treatments are discussed below under the relevant treatment.

Surgical Treatments Analyzed - Descriptions and Outcomes

The surgical treatments analyzed fell into four categories: retropubic suspensions, slings, injectable agents and artificial urinary sphincters (AUS). Within each class, modifications of these treatments were analyzed where appropriate. For some categories, only minimal data were available. As noted in the methods section, definitions of cured, dry and improved were those of the authors.

In this section, brief descriptive results are provided for outcomes. The complete results are provided in Chapter 3 and Appendices A7-A16.

Retropubic Suspensions

Although the techniques for performing retropubic suspensions were essentially unchanged since the 1997 Guideline, the Panel elected to determine if there were any new studies since that analysis that would result in significantly different outcomes. Data from three categories of retropubic suspensions were analyzed: 1) open suspensions regardless of type (including Burch suspensions); 2) open Burch suspensions alone; and 3) laparoscopic suspensions.

The Panel's meta-analysis estimated cured/dry rates at 12 to 23 months based on 1,085 patients for open suspensions with no concomitant prolapse treatment to be 82% (CI: 74%-87%) while cured/dry rates for laparoscopic suspensions were 69% (368 patients; CI: 52%-84%) (Table 1). At 24 to 47 months, the cured/dry rates were similar among all procedures, ranging from 74% to 76%. At 48 months or longer, cured/dry rates for all open procedures were 73%. No data were available for laparoscopic procedures. These rates are similar to those reported for retropubic suspensions in the previous Guideline, in which estimated cured/dry rates were 84% at all time points.⁴

The meta-analysis estimate of postoperative urge incontinence was 14% from data from 186 patients (CI: 6%-25%) with pre-existing urge incontinence when treated with open retropubic suspensions, while de novo urge incontinence and “unspecified” urge incontinence was estimated in 8% (713 patients; CI: 5%-12%) and 41% of patients (305 patients; CI: 30%-54%), respectively (Table 3). Of patients undergoing laparoscopic retropubic suspensions, the meta-analytic results indicate that an estimated 5% of patients (CI: 1%-14%) will experience de novo urge incontinence and approximately 6% (CI: 1%-14%) will have “unspecified” urge incontinence. There were few data available for laparoscopic retropubic suspensions or for longer term outcomes of open retropubic suspensions (for longer term outcomes on urge incontinence, see Chapter 3). Based on 1,154 patients in 18 studies, retention could occur in 3% to 4% of patients (Table 4). The most common complications and estimated rates of occurrence for open retropubic suspensions determined in the meta-analysis (see Chapter 3) were febrile complications (8%), urinary tract infection (13%), bladder injury (4%) and voiding dysfunction (9%). Laparoscopic suspensions appeared to have a lower overall risk of febrile complications (0% reported) and urinary tract infection (2%), although these estimates were based on limited data. Ureteral injury was estimated to occur in 4-11% of patients receiving laparoscopic retropubic suspensions (see later discussion in Chapter 3), but only 1% of patients receiving open suspensions. Again, these estimates were based on a very small number of patients.

For patients with concomitant prolapse treatment, the estimated cured/dry rates for open retropubic suspensions, Burch suspensions and laparoscopic suspensions were all 88% at 12 to 23 months and 83% to 85% at 24 to 47 months (Table 2). The cured/dry rate was estimated to be 67% (1,072 patients; CI: 56%-76%) for all open retropubic suspensions at 48 months or longer, and data were insufficient for an approximation of efficacy for laparoscopic therapy at 48 months

or longer. The postoperative urge incontinence rate was based on 143 patients with pre-existing urge incontinence who were treated with open retropubic suspensions with concurrent prolapse repair; the rate of occurrence was approximately 22% (CI: 4%-56%). Further, the analysis estimates 14% of patients (457 patients; CI: 8%-21%) may experience de novo urge incontinence and 13% of patients (256 patients; CI: 7%-22%) may report “unspecified” urge incontinence (Table 3). By comparison, the results estimate that 11% of patients treated with laparoscopic suspensions will have de novo urge incontinence (344 patients; CI: 6%-17%); data were unavailable or insufficient for the other urge incontinent outcomes with laparoscopic retropubic suspensions (for longer term outcomes on urge incontinence, see Chapter 3). Retention was estimated in 1% to 2% of patients (Table 4).

Slings

Autologous Fascial Slings

Efficacy data were available for a variety of types of autologous fascial slings, including suprapubic slings with bone anchors, autologous vaginal wall slings with or without bone anchors and the general category of autologous fascial slings without bone anchors (detailed outcomes for the different types of autologous fascial slings are provided in Chapter 3).

Most of the available studies described patients treated with autologous slings without bone anchors. For patients without concurrent prolapse treatment, the estimated cured/dry rates ranged between 90% at 12 to 23 months and 82% at 48 months or longer (Table 1). The Panel’s meta-analysis estimated rates of postsurgical urge incontinence were 33% in patients with pre-existing urge incontinence and de novo urge incontinence in 9% of patients without pre-existing urge incontinence (Table 3). The estimated rate of retention was 8% (Table 4). Complications estimates for autologous fascial slings without bone anchors were generally infrequent and

included urinary tract infection (11%), bladder injury (4%) and wound complications (8%). There were also a few studies published between 2001 and 2003 reporting data on a small number of patients who received autologous fascial vaginal wall slings with or without bone anchors. Complete data are provided in Chapter 3.

For patients treated with autologous slings without bone anchors and a concurrent prolapse treatment, cured/dry rates ranged from 85% to 92%, although these estimates were based on a very small number of patients (Table 2). Based on the results of the meta-analysis, approximately 10% of patients could experience de novo urge incontinence, and an estimated 5% of patients will be subject to retention (Table 3).

Cadaveric Slings

Cadaveric slings came into wide use following a report by Handa et al.,¹⁰ and other authors have since reported favorable results using this procedure.^{11, 12} However, the long-term durability of these procedures has been questioned,^{13, 14} with reports of graft failure^{15, 16} and declining success rates over time^{17, 18} (for a more complete discussion on the use of cadaveric slings, see Chapter 3). The use of these materials has dramatically declined over time as a result of these concerns, thus severely limiting data available for analysis.

Based on the limited data available for analysis, the estimated cured/dry rate for patients undergoing cadaveric slings without bone anchors and no concomitant prolapse treatment was 74% at 12 to 23 months and 80% at 24 to 47 months (Table 1). There were no data for longer term efficacy (48 months or longer) for cadaveric slings, and few studies reported data on retention, urge incontinence or complications.

For patients with concomitant prolapse treatment, the Panel's meta-analysis estimates of cure/dry rates were 82% (234 patients CI: 77%-86%) at 12 to 23 months using a cadaveric sling

with bone anchors, whereas the rate was 58% based on patients from three studies totaling 133 patients (CI: 36%-78%) where bone anchors were not utilized (Table 2). Despite the fact that these confidence intervals barely overlap, the consensus of the Panel is that these represent statistical aberrations inherent in evidence combination and are likely not representative of a true difference in outcomes. There were no data for bone-anchored slings beyond two years. At 24 to 47 months, for patients undergoing a cadaveric sling procedure without bone anchors in addition to prolapse treatment, the cured/dry rate was 64%, and at > 48 months based on 13 patients, only an estimated 31% receiving a cadaveric sling without bone anchor will be cured/dry.

Little is known about the graft-host relationship and possible mechanisms of graft degradation for cadaveric materials. In addition, processing and storage of these materials is variable, which could account for the disparity of results as reflected by the wide CIs in our analysis. There were insufficient data to assess the long-term efficacy of these procedures, with very few studies reporting results at 48 months or longer. Furthermore, the risks of disease transmission with these materials remain unknown. Traces of genetic material have been isolated from commercially available cadaveric sling materials¹⁹ although there have been no reports of disease transmission related to cadaveric grafts in the urologic literature.

There were few complications reported in the literature for procedures using cadaveric sling materials. Vaginal extrusion was reported in one study,²⁰ but erosion of cadaveric materials into the urinary tract was not identified in this meta-analysis. Other reported complications were similar to other procedures for the surgical correction of SUI. When these materials have been used with concomitant prolapse repair, complications such as infection and graft extrusion have been reported.²¹

Synthetic Slings

Efficacy data were available for synthetic slings placed at the bladder neck and synthetic slings placed at the midurethra. Outcomes are discussed separately for each of these procedures.

Synthetic Slings at the Bladder Neck

Efficacy data were available for synthetic slings at the bladder neck with or without bone anchors; most of the data came from studies involving synthetic slings without bone anchors. With this procedure, the estimated cured/dry rate based on 349 patients in nine studies without prolapse treatment was 73% (CI: 64%-80%) at 24 to 47 months; longer term data were not available (Table 1). De novo urgency was approximated at 12% of patients (132 patients; CI: 6%-20%) at 12 to 23 months; there were limited data on other urge incontinence outcomes (Table 3). The retention rate was an estimated 9% (360 patients; CI: 5%-15%) (Table 4). The most common complications occurring with synthetic slings at the bladder neck without bone anchors (provided in Chapter 3) were urinary tract infection (10%) and erosion/extrusion (5% for urethral/bladder, 8% for vaginal and 17% for unknown). However, because only studies that report a given complication were included in the analysis and many of these studies were small case series, these percentages may represent an overestimation of the risk of these complications. Despite these limitations, these data suggest an increased probability of urinary tract erosion following synthetic slings placed at the bladder neck.

For those treated with synthetic slings at the bladder neck with concurrent prolapse treatment, the meta-analysis estimated cured/dry rates of 73% to 75% at 24 months and longer (Table 2). Estimates of postoperative urge incontinence based on 119 patients with pre-existing urge incontinence in three studies was 29% (CI: 16%-46%), and estimates suggested that only

15% of patients (150 patients; CI: 5%-31%) will experience de novo urge incontinence (Table 3). The estimated retention rate was 10% (422 patients; CI: 5%-18%) (Table 4).

Synthetic Slings at the Midurethra

Since the publication of the 1997 guideline, there has been a proliferation of new modifications to the pubovaginal sling that have largely replaced the retropubic suspension and the autologous sling as the primary procedures for SUI. In these procedures the synthetic sling is placed at the midurethra as opposed to the bladder neck. These procedures are performed using one of two techniques –transvaginal/retropubic or transobturator. In the retropubic technique, trocars or long needles are passed at the midurethra through the retropubic space from the vagina to the abdomen or from the abdomen to the vagina. In the transobturator technique, the slings are passed with a curved trocar from the vagina behind the ischium (inside-out) or from the ischium to the vagina (outside-in). At the time of this analysis, data on the transobturator technique was limited, with insufficient numbers of patients having long-term follow-up to reach any conclusions regarding efficacy (see final section of this document for further discussion of these procedures).

For the transvaginal/retropubic technique, the Panel's meta-analysis estimated cured/dry rates in patients without prolapse treatment ranging from 81% to 84% at all time points (Table 1), which is comparable to the medium-term results for the Burch suspensions and autologous fascial slings. De novo urge incontinence was projected in 6% of patients (323 patients; CI: 3%-10%) (Table 3) while retention estimates were 3% of patients (2119 patients; CI: 2%-4%) (Table 4); insufficient data were available for an estimate of resolution of pre-existing urgency, with only 1 group of 25 patients providing data. Complication rates (see Chapter 3) included bladder injury as defined by the study authors (6%), urinary tract infection (11%) and extrusions

(7% for vaginal extrusions and 1% for unknown). Wound complications were also reported in the literature. Thirteen case reports identified the complications of urethral or bladder erosion of mesh into the urinary tract which occurred in over half of a cohort of 33 patients. Unfortunately, the probability of urinary tract erosion was unable to be calculated precisely from the database as all of these were reports of individual cases or small case series which would result in an overestimation of the risk of these complications. Similar efficacy results were found for those treated with midurethral synthetic slings with concurrent prolapse treatment.

Mesh in pelvic floor surgery:**

Recently, the U.S. Food and Drug Administration (FDA) released a warning position statement concerning the use of mesh materials in stress incontinence surgery and pelvic organ prolapse surgery. They noted over 1,000 reported complications of vaginal and urinary erosion as well as bowel and vascular injuries (<http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html>). This data has been extracted from the FDA Manufacturer and User Facility Device Experience Database (MAUDE) database, which promotes voluntary reporting of complications. The Panel has reviewed this statement and the results of this meta-analysis. Based on this review, the Panel has reached the following conclusions:

- 1) In this meta-analysis, the midurethral slings had an efficacy comparable to autologous slings in the surgical treatment of SUI.
- 2) Several “versions” of the midurethral sling procedures do not have similar long-term efficacy data.

****The FDA issued an updated warning in July 2011 regarding the use of vaginal mesh. Please read the alert on the cover of this guideline.**

- 3) There are complications that may occur that are unique to specific mesh materials; however, these complications appear to be rare. Intraoperative use of cystoscopy can be performed to minimize the risk of urinary tract injury or erosion.
- 4) The midurethral sling is an alternative in the management of SUI. The incidence and implications of these complications along with the more rapid recovery and more efficient return to normal voiding after surgery should be discussed with patients before surgery.

Injectable Agents

Injectable agents may provide immediate relief for some patients and are an option for patients who do not wish to undergo more invasive surgery and who understand that both efficacy and duration are inferior to surgery. Other possible indications for the use of injectable agents include patients who are elderly, those who are at high anesthetic risk or those willing to accept an improvement in their incontinence without necessarily achieving dryness.

For this analysis, injectable agents were subdivided into collagen (bovine gluteraldehyde cross-linked) and other nondegradable synthetic agents. The literature reviewed for this guideline offered minimal new data, with sufficient data available for an analysis of only collagen. The anticipated efficacy for patients treated with collagen without concomitant prolapse treatment declined over time, from 48% at 12 to 23 months to 32% at 24 to 47 months (Table 1). The estimated rates of de novo and unspecified urge incontinence as well as the rates of complications were low.

Very limited information is available for the other injectable agents with the exception of the multicenter trials that won approval for these agents by the U.S. FDA. These include carbon-coated zirconium beads in beta-glucan gel²² and calcium hydroxylapatite.²³ Data regarding newer agents under FDA review or not yet in the literature were not included. There were limited data with which to assess the long-term safety and efficacy of injectable agents. These agents are an option for women who require or prefer a minimally invasive procedure under local anesthesia.

Artificial Urinary Sphincters

In the U.S., use of the AUS is generally restricted to children with nonfunctioning urethras (i.e., those with spina bifida), in adults with nonfunctioning urethras secondary to trauma to the nerves of the pelvis such as following automobile accidents or in male adults with postprostatectomy incontinence. Data on use of the AUS in the index patient are limited. It is occasionally used in a patient with severe intrinsic sphincteric deficiency who has failed other surgical procedures, or patients with significant SUI and poor bladder contractility such as those with diabetes or back injury. Although limited, available data on the AUS in over a decade of use demonstrate that it can be a valuable therapy with a high degree of effectiveness. Erosion, infection and device malfunction are potential complications. Based on the only recent study on complications, an anticipated erosion/extrusion rate was computed to be 28%.²⁴ With respect to the index patient, the AUS might be useful in the Valsalva-voiding woman who must abdominally strain to empty the bladder. When the cuff is opened for voiding, the AUS is likely nonobstructive to the bladder in contrast to slings where straining may cause obstruction to the flow of urine. The Panel feels that the role of the AUS is limited.

Treatment Guidelines for the Index Patient

The Panel updated existing guideline statements and developed new statements. Amendments to 1997 Standards, Recommendations and Options are indicated (words that are in italics denote changes from the 1997 guideline document to improve clarity).

Standard: The patient should be counseled regarding the surgical and nonsurgical options including both benefits and risks. Choice of the procedure should be made as a collaborative effort between the surgeon and patient and should consider both patient preferences and the surgeon's experience and judgment.

[Based on Panel consensus]

Standard: Patients with urge incontinence without stress incontinence should not be offered a surgical procedure for stress incontinence. The index patient has stress urinary incontinence with or without prolapse. The use of a prophylactic anti-incontinence procedure in the patient with occult incontinence with high grade prolapse is not the guideline index patient and the panel does not have an opinion about prophylactic incontinence surgery.

[Based on Panel consensus]

Recommendation: Synthetic sling surgery is contraindicated in stress incontinent patients with a concurrent urethrovaginal fistula, urethral erosion, intraoperative urethral injury and/or urethral diverticulum.

[Based on Panel consensus]

Although there is no peer-reviewed literature that specifically evaluates these uncommon conditions, the Panel believes that using synthetic material in these circumstances may place the patient at higher risk for subsequent urethral erosion, vaginal extrusion, urethrovaginal fistula and foreign body granuloma formation. In such patients, the Panel believes that autologous fascial and alternative biologic slings are an option in the treatment of concomitant stress incontinence. The decision to use these materials should be based on the judgment of the surgeon and made in the best interests of the patient.

Standard: Intraoperative cystourethroscopy should be performed in all patients undergoing sling surgery.

[Based on Panel consensus]

For detection of potential intraoperative complications, the bladder and urethra should be inspected either with a rigid or flexible cystoscope prior to the conclusion of the procedure. A short beak rigid cystoscope or flexible fiberoptic cystoscope provides optimal visualization of the female urethra.

Option: The five major types of procedures (injectables, laparoscopic suspensions, midurethral slings, pubovaginal slings and retropubic suspensions), although not equivalent, may be considered for the index patient.

[Based on Panel consensus]

Newer techniques and materials for the surgical treatment of stress incontinence such as midurethral synthetic slings have been developed. For the index patient, the Panel believes that these techniques, materials and accompanying physician expertise and

experience offer a number of advantages that include shorter operative time, shorter recovery time and less short-term morbidity; however, urethral erosion and vaginal extrusion of the synthetic material may occur, which can be very difficult to treat. In addition, perforation of bowel and blood vessels, which pose a life-threatening risk, may result from this procedure. Longer term follow-up is needed before any definitive statements regarding the long-term efficacy and life-long risk of erosion with these procedures can be made.

Option: The artificial urinary sphincter may be indicated in certain circumstances.

[Based on evidence and Panel opinion]

The Panel considers the use of the AUS in the index patient as an option, with a role limited to patients not amenable to treatment with other procedures.

Option: Stress incontinence procedures may be considered for patients with mixed incontinence with a significant stress incontinence component.

[Based on review of the data and Panel consensus]

Ample support exists for the role of surgery in mixed incontinence²⁵ The meta-analysis estimate of postoperative urge incontinence was 14% from data from 186 patients (CI: 6% - 25%) with pre-existing urge incontinence when treated with open retropubic suspensions while others have reported disparate outcomes.²⁶

Recommendation: Surgical procedures for SUI and prolapse may be safely performed concomitantly in appropriately selected women. Tensioning of any sling should not be performed until prolapse surgery is completed.

[Based on Panel consensus]

Recommendations for Future Research and Reporting

Recommendations to Editors and Reviewers

Although more than a decade has passed since the recommendations for improving the quality of data from clinical trials and studies were proposed by Leach et al.,⁴ very little progress has been made by editors and reviewers in instituting these recommendations.²⁷ Furthermore, the FDA has not altered the approval process as discussed below. Thus, again, the Panel members were extremely disappointed in data available for meta-analysis. In addition to the specific data outlined by Leach et al.⁴ in the original Panel report, editors and their reviewers should require:

- Defined outcome measures obtained preoperatively and followed postoperatively
 - validated questionnaires
 - bladder diary
 - pad test
 - exam with full bladder
- A minimum follow-up of at least 12 months of all surgically treated patients for reporting of efficacy data
- A grading of the degree of prolapse (anterior, posterior, apical) as determined by preoperative pelvic examination recorded on all patients

For adverse event data, complications should be categorized as occurring intraoperatively or postoperatively. It is essential to report the following adverse event data:

- Overactive bladder symptoms, which should include persistent overactivity (already present preoperatively) or de novo overactivity (occurring as a complication of the surgery)
- Persistent or de novo other lower urinary tract symptoms
- Urinary retention of greater than four weeks and/or requiring intervention
- Infection (reported as wound infection, vaginal infection, symptomatic urinary tract infection, pelvic abscess, etc.)
- Fever (sepsis)
- Postoperative pain, bleeding, thromboembolus formation (lower extremity, pulmonary or other)
- Lower urinary tract or vaginal injury or erosion
- Refractory pain
- Other serious complications, including vascular or bowel injury, death

The profession at large and the individual physician should insure the safety and efficacy of any new device or sling. If safety and efficacy has not been shown with reasonable certainty, the new treatment should only be performed as part of clinical research studies and/or with informed consent recognizing that safety and/or efficacy has not been demonstrated.

Transobturator Tape Procedures

As previously discussed, modifications to the pubovaginal sling since the 1997 guideline include development of two minimally invasive procedures for the surgical treatment of SUI: the tension-free vaginal tape procedure introduced in 1996,²⁸ and the transobturator technique, introduced in 2001.²⁹⁻³¹

In the development of this guideline, the Panel established June 2005 as a cut-off date for literature review. At that time, the transobturator was a novel procedure with limited information available in the published literature, precluding inclusion of the procedure in the data analyses. Since that deadline, numerous articles have been published in the peer-reviewed literature regarding the transobturator procedure. The Panel is very aware of the importance of the transobturator procedure in the current practice of urology and urogynecology.

Conflict of Interest Disclosures

All panel members completed Conflict of Interest disclosures. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

Consultant or Advisor: Rodney Appell, Boston Scientific (C), Allergan (C), Astellas (C), Bayer, Schering-Plough (C), Pfizer (C), American Medical Systems (C); Roger R. Dmochowski, Novartis (C), Pfizer (C), Astellas (C), Watson Pharmaceuticals (C), Lilly (C); Mickey M. Karram, Astellas (C), Cooper Surgical (C), EWH&U (C); Karl M. Lubner, Watson Pharmaceuticals (C), Indevus (C), Pfizer (C), Astella (C); David R. Staskin, Pfizer (C), GlaxoSmithKline (C), Astellas (C), Watson (C), Allergan (C), American Medical Systems (C); Saad Juma, Coloplast corporation (C), Contura (C); J. Christian Winters, Astellas (C); Jerry G. Blaivas, Navasys Medical (C), Bayer (C), Pfizer (C), Endogun (C); Eric Scott Rovner, Pfizer (C), Allergan (C), Astellas (C), Tengion (C). **Investigator:** Rodney Appell, Solace, Inc. (C), Novasys Medical, Inc. (C); Roger R. Dmochowski, Allergan (C); Saad Juma, Solace Therapeutics (C), Contura (C), Bioform (C); Eric Scott Rovner, Pfizer (C). **Scientific Study or Trial:** Eric Scott Rovner, Pfizer, (C), Solace, (C), Contura (C); J. Christian Winters, Solace Thera (U). **Meeting Participant or Lecturer:** Eric Scott Rovner, Allergan (C); **Other:** Rodney Appell, American Medical Systems (C), Boston Scientific Corporation (C); Jerry G. Blaivas, HDH (U); Mickey M. Karram, E-Medco (C), Ethicon Women's Health & Urology(C), Cooper Surgical (C), Astella (C); Linda E. Whetter, Zola Associates (C).

1 **Acknowledgments and Disclaimers: Guidelines for the Management**
2 **of Female Stress Urinary Incontinence: 2009 Update**

3 This document was written by the Female Stress Urinary Incontinence Update Panel of the
4 American Urological Association Education and Research, Inc., which was created in 2002. The
5 PGC of the AUA selected the committee chair. Panel members were selected by the chair.
6 Membership of the committee included urologists and gynecologists with specific expertise on
7 this disorder. The mission of the committee was to develop recommendations that are analysis-
8 based or consensus-based, depending on Panel processes and available data, for optimal clinical
9 practices in the diagnosis and surgical treatment of female SUI. This document was submitted
10 for peer review to 76 urologists and other healthcare professionals. After the final revisions were
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15 This report is intended to provide medical practitioners with a consensus of principles
16 and strategies for the surgical treatment of female stress urinary incontinence. The report is based
17 on current professional literature, clinical experience and expert opinion. It does not establish a
18 fixed set of rules or define the legal standard of care, and it does not preempt physician judgment
19 in individual cases.

Table 1. Cured/dry analysis – No concurrent prolapse treatment*

	12-23 months		24-47 months		≥48 months	
	G/P	Median % (CI 2.5% - 97.5%)	G/P	Median % (CI 2.5% - 97.5%)	G/P	Median % (CI 2.5% - 97.5%)
Suspensions						
All Open Retropubic	15/1085	82% (74 - 87)%	13/803	76% (68 - 82)%	17/1259	73% (64 - 77)%
Burch	14/1070	81% (73 - 87)%	12/775	76% (68 - 83)%	13/1065	73% (65 - 80)%
Laparoscopic	9/368	69% (52 - 84)%	4/172	74% (61 - 85)%		
Slings						
Autologous fascial						
without bone anchors	4/342	90% (76 - 98)%	6/232	81% (72 - 88)%	4/368	82% (67 - 93)%
vaginal wall slings w/without bone anchors	1/39	79% (65 - 90)%			1/29	96% (85 - 100)%
vaginal wall slings with bone anchors			1/58	79% (68 - 88)%		
Cadaveric without bone anchors	1/104	74% (65 - 82)%	2/71	80% (43 - 98)%		
Synthetic at bladder neck						
with bone anchors	2/34	88% (71 - 97)%			1/27	92% (78 - 98)%
without bone anchors			9/349	73% (64 - 80)%		
Synthetic at midurethra	14/1215	84% (78 - 89)%	7/483	81% (72 - 88)%	3/199	84% (77 - 89)%
Injectables						
Collagen	7/340	48% (41 - 55)%	4/210	32% (24 - 42)%	1/40	30% (18 - 45)%

G=number of groups/arms in analysis; P=number of patients in analysis

*By any evaluation method, including subjective and objective

Table 2. Cured/dry analysis: ANY patient in the group/arm receiving concurrent prolapse treatment*

	12-23 months			24-47 months			≥48 months		
	G/P	Median % (CI 2.5% - 97.5%)		G/P	Median % (CI 2.5% - 97.5%)		G/P	Median % (CI 2.5% - 97.5%)	
Suspensions									
All Open Retropubic	9/517	88% (83 - 92)%		9/403	83% (75 - 90)%		13/1072	67% (56 - 76)%	
Burch	9/517	88% (83 - 92)%		7/333	85% (75 - 93)%		12/954	65% (53 - 74)%	
Laparoscopic	12/564	88% (85 - 91)%		7/359	83% (73 - 91)%		1/34	88% (74 - 96)%	
Slings									
Autologous fascial									
without bone anchors	3/78	92% (82 - 97)%		1/80	85% (76 - 92)%				
vaginal wall slings w/without bone anchors	1/20	70% (48 - 86)%		2/60	89% (64 - 99)%		1/82	95% (89 - 98)%	
vaginal wall slings with bone anchors, suprapubic	1/19	99% (88 - 100)%		1/9	87% (59 - 99)%				
Cadaveric									
with bone anchors -transvaginal	1/234	82% (77 - 86)%							
without bone anchors	3/133	58% (36 - 78)%		2/92	64% (21 - 95)%		1/13	31% (11 - 58)%	
Homologous dermis without bone anchors				1/19	89% (70 - 98)%				
Synthetic at bladder neck									
with bone anchors-suprapubic							1/49	85% (74 - 93)%	
with bone anchors- transvaginal				1/32	81% (65 - 92)%				
without bone anchors	1/20	94% (79 - 99)%		3/184	75% (56 - 90)%		3/182	73% (62 - 82)%	
Synthetic at midurethra	14/1089	85% (80 - 89)%		11/881	87% (81 - 91)%		2/101	76% (64 - 85)%	
Other Sling	1/126	92% (86 - 96)%							

G=number of groups/arms in analysis; P=number of patients in analysis

*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Table 3. Urge incontinence outcomes at 12-23 months

	No Prolapse Treatment					
	De Novo		Pre-Existing		Unspecified	
	G/P	Median % (CI 2.5% - 97.5%)	G/P	Median % (CI 2.5% - 97.5%)	G/P	Median % (CI 2.5% - 97.5%)
Suspensions						
All Open Retropubic	10/713	8% (5 - 12)%	5/186	14% (6 - 25)%	4/305	41% (30 - 54)%
Burch	9/695	8% (5 - 11)%	3/108	17% (4 - 40)%	4/305	41% (30 - 54)%
Laparoscopic	2/112	5% (1 - 14)%			2/100	6% (1 - 14)%
Slings						
Autologous fascial						
without bone anchors	4/329	9% (6 - 13)%	4/358	33% (28 - 40)%		
vaginal wall slings w/without bone anchors			1/13	9% (1 - 31)%		
vaginal wall slings with bone anchors						
Cadaveric without bone anchors	1/25	28% (13 - 47)%	1/38	21% (10 - 36)%		
Synthetic at bladder neck with bone anchors			1/6	96% (67 - 100)%		
Synthetic at bladder neck without bone anchors	4/132	12% (6 - 20)%	1/24	17% (6 - 35)%		
Synthetic at midurethra	7/323	6% (3 - 10)%	1/25	44% (26 - 63)%	2/532	22% (3 - 58)%
Other Sling						
Injectables						
Collagen	1/337	13% (10 - 17)%			1/50	8% (3 - 18)%
Any Prolapse Treatment*						
Suspensions						
All Open Retropubic	10/457	14% (8 - 21)%	2/143	22% (4 - 56)%	2/256	13% (7 - 22)%
Burch	9/417	14% (8 - 22)%	1/25	48% (30 - 67)%	2/256	13% (7 - 22)%
Laparoscopic	5/344	11% (6 - 17)%			1/32	4% (0 - 14)%
Slings						
Autologous fascial						

without bone anchors	2/97	10%	(4 - 19)%						
vaginal wall slings w/without bone anchors	3/65	13%	(2 - 36)%	2/15	47%	(21 - 75)%			
vaginal wall slings with bone anchors suprapubic	1/9	13%	(1 - 41)%						
Cadaveric with bone anchors - transvaginal	1/238	6%	(3 - 9)%						
Homologous tissue (dermis) without bone anchors	1/5	22%	(2 - 63)%						
Synthetic at bladder neck without bone anchors	4/150	15%	(5 - 31)%	3/119	29%	(16 - 46)%			
Synthetic at midurethra	11/805	11%	(7 - 16)%	5/107	52%	(38 - 66)%	2/174	9%	(1 - 38)%

G=number of groups/arms in analysis; P=number of patients in analysis

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Table 4. Retention *					
	No prolapse treatment			Any prolapse treatment**	
	G/P	Median % (CI 2.5%- 97.5%)		G/P	Median % (CI 2.5% - 97.5%)
Suspensions					
All Open Retropubic	8/619	4% (1 - 8)%		13/851	1% (1 - 3)%
Burch	5/347	3% (1 - 7)%		10/710	1% (1 - 3)%
Laparoscopic	5/188	4% (1 - 8)%		11/482	2% (1 - 4)%
Slings					
Autologous fascial					
without bone anchors	8/480	8% (4 - 15)%		3/301	5% (2 - 11)%
vaginal wall slings w/without bone anchors	2/68	2% (0 - 8)%		3/142	5% (1 - 17)%
Suprapubic				1/25	1% (0 - 9)%
Cadaveric without bone anchors				1/26	1% (0 - 10)%
Synthetic at bladder neck					
with bone anchors - suprapubic				1/49	4% (1 - 12)%
with bone anchors - transvaginal				2/99	1% (0 - 6)%
without bone anchors	4/360	9% (5 - 15)%		7/422	10% (5 - 18)%
Synthetic at midurethra	17/2119	3% (2 - 4)%		11/1107	3% (2 - 5)%
Injectables					
Collagen	2/104	1% (0 - 5)%			

G=number of groups/arms in analysis; P=number of patients in analysis

* Duration greater than 28 days or requiring intervention

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

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Abbreviations and Acronyms

AUA	=	American Urological Association
AUS	=	artificial urinary sphincter
CI	=	confidence interval
etc.	=	et cetera; and the rest
et al.	=	and others
FDA	=	Food and Drug Administration
G	=	groups
i.e.	=	that is
P	=	patients
PGC	=	Practice Guidelines Committee
RCT	=	randomized controlled trial
sine qua non	=	an essential or indispensable element or condition
SUI	=	stress urinary incontinence
U.S.	=	United States
w/	=	with

Chapter 2. Methodology

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This guideline used an explicit approach to address the relevant factors for choosing among alternative interventions.¹ These factors include outcomes of the interventions, patient preferences, and the relative priorities of interventions given limited health care resources. In developing the guideline, the Panel used scientific evidence to estimate outcomes of treatment modalities as accurately as possible. Panel members themselves served as proxies for patients in considering preferences with regard to health and economic outcomes.

The steps taken to develop this guideline are summarized in Chapter 1 and described in detail in the present Chapter. Steps included problem definition, literature search, data extraction, systematic evidence combination, guideline generation, approval, and dissemination.

Problem Definition

This update guideline was based on the original AUA guideline on the Surgical Management of Female Stress Urinary Incontinence published in 1997. The methodology was similar to that used in the previous guideline. Like the previous guideline, the analysis was limited to surgical treatments. Non-surgical therapies such as biofeedback, pessaries, and pelvic floor exercises were not examined. Unlike the previous guideline, the update includes an analysis of patients who also received surgical therapy for prolapse although it doesn't attempt to compare their efficacy. This update is also restricted to therapies introduced since the last guidelines report and to the therapies that appeared to be the most efficacious in the previous guideline.

Like the previous guideline, the intention was to determine the impact of the various available treatments on the outcomes of importance to patients. The efficacy outcomes examined were resolution, improvement, and recurrence of incontinence and urgency. The panel also examined the impact of treatment on prolapse resolution, and post-operative recurrence or new onset. However, insufficient usable information was available to make meaningful estimates for these prolapse outcomes. The panel also attempted to estimate the occurrence of side effects and complications of treatments. Incontinence treatments analyzed included retropubic suspensions, slings, injection therapy, and artificial sphincters. The panel excluded treatments that were not generally available in the US and were not expected to be approved for general use by the time of the release of the guideline. The panel also decided not to update outcomes for treatments that were covered in the previous guideline, namely anterior repairs and transvaginal suspensions, but were no longer considered contemporary surgical treatments. Anterior repairs for prolapse reduction in conjunction with other surgical treatments for incontinence were included as prolapse surgeries. A wide variety of procedures were used

correct prolapse including hysterectomy, and position specific repairs (e.g. anterior, posterior, enterocele, and apical).

Literature Search and Data Extraction

The review of the evidence began with a literature search and data extraction. Articles were selected from a database, based on articles retrieved for the previous guideline and a series of four Medline searches beginning in December 2002 and concluding in June 2005. The searches were limited to human subjects, English language, publication date on or after 1990, and the mesh term “female”. Searches were containing the mesh heading “urinary incontinence, stress”. Additional searches were done using the terms “urinary incontinence, stress”, “stress incontinence”, and “urinary-incontinence” in any field. A total of 7,111 citations and abstracts were reviewed for relevance. The abstracts were reviewed by the panel chairs and articles were selected for data extraction if any chair felt it might have useful data. In total 1302 citations entered the extraction process. A data extraction form was developed, tested and revised (see appendix A4. The panel was trained in data extraction. After double review and quality control of the initial extractions, single panel members extracted data from the articles with over 25% cross checked by another panel member. The final versions of the extracted data were entered into a Microsoft Access® (Microsoft, Redmond, WA) database. The Panel met in person and via conference calls to review the extracted data. Inconsistencies in data recording were reconciled, extraction errors were corrected, and some articles were excluded. Reasons for excluding articles from further analysis were as follows:

1. The article did not provide usable data on the outcomes of interest.

2. The article did not deal with stress incontinence, e.g. articles that dealt with patients who only had prolapse.
3. The article dealt only with basic science or epidemiology.
4. The treatments used were not current or were not the focus of the analysis.
5. The article was a review article or reported data reported elsewhere.
6. The treatment discussed was not available in the US or expected to be available when the guideline was scheduled for release.

A total of 436 of the articles were accepted. An additional 155 articles were accepted for complications data only. These 155 articles were otherwise acceptable but had insufficient follow-up for efficacy outcomes. Articles were only accepted for efficacy data if there was a minimum follow-up of at least 1 year. A complete list of the articles used is in Appendix A5, ordered by primary author, and in Appendix A6, ordered by reference number. Note that some articles excluded from evidence combination remained candidates for discussion in the text of the guideline.

Evidence Combination

The analytic goals were expanded from the previous guideline. However, as mentioned above two patient groups were analyzed, one where no patients received treatment for prolapse, and another where some or all received prolapse repairs. To generate an outcome table, estimates of the probabilities and/or magnitudes of the outcomes are required for each intervention. Ideally, these come from a synthesis or combination of the evidence. Such a combination can be performed in a variety of ways depending on the nature and quality of the evidence. For example, if there is one good randomized controlled trial, the results of that trial alone may be used in the outcome table while findings of other studies of lesser quality are

ignored. Alternatively, if there are no studies of satisfactory quality for certain outcome table cells or if available studies are not commensurable, expert opinion may be used to complete those cells. Finally, if a number of studies have some degree of relevance to a particular cell or cells, then meta-analytic mathematical methods may be used.

A variety of specific meta-analytic methods are available, and selection of a particular method depends on the nature of the evidence. For this *guideline*, the panel elected to use the confidence profile method,^{2,3} which provides methods for analyzing data from studies that are not randomized controlled trials. The Fast*Pro computer software⁴ was used in the analysis.

Although a number of randomized controlled trials were uncovered in the literature search, there were insufficient numbers on the same topic to warrant meta-analysis. Discussions of the results of some of these trials are included where relevant in the text of this document. Meta-analysis was performed using the individual arms of the controlled trials and the clinical series where similar patients were similarly treated. The Fast*Pro software was used to perform the meta-analyses. Series that were combined frequently showed very different results implying site-to-site variations that may have resulted from differences in patient populations, in how the intervention was performed, or in the skill of those performing the intervention. Given these differences, a random-effects, or hierarchical, model was used to combine the studies.

A random-effects model assumes that there is an underlying true rate for the outcome being assessed for each site. It further assumes that this underlying rate varies from site to site. This site-to-site variation in the true rate is assumed to be normally distributed. The method of meta-analysis used in analyzing the data attempts to determine this underlying distribution.

The results of the confidence-profile method are probability distributions that are described using the median of the distribution with a confidence interval. In this case, the 95% confidence

interval indicates that the probability (Bayesian) of the true value being outside the interval is 5%. These Bayesian confidence intervals are sometimes called credible intervals.

The Bayesian method of computation assumes a “prior” distribution that reflects knowledge about the probability of the outcome before the results of any experiments are known. The prior distributions selected for this analysis are among a class of “noninformative” prior distributions, which means that they correspond to little or no prior knowledge. The existence of such a prior distribution can cause small changes in results, particularly for small studies. The prior distribution for all probability parameters is Jefferey’s prior (beta distribution with both parameters set to 0.5). The prior for the variance for the underlying normal distribution is gamma distributed with both parameters set to 0.5.

In addition to the outcomes table, some graphs showing the results were developed to visually show some treatment differences.

It is important to note that, for certain outcomes, more data were reported for one or another treatment modality. While resulting confidence intervals reflect available data, the probabilities for certain outcomes can vary widely from study to study within one treatment modality. For example, differences in patient selection may have had more weight in analyses than differing treatment effects. Nevertheless, the results obtained reflect the best outcome estimates presently available.

Patient Groups

The panel attempted to evaluate outcomes based on a variety of patient characteristics including type of incontinence, previous treatment, presence of prolapse, prior pregnancy and severity of incontinence. However, in most cases, the outcomes data were not fully or consistently stratified by these conditions. Ultimately, patient groups were divided into 2

categories: groups where no patients received treatment for prolapse (comparable to the previous guideline) and groups where some or all patients received treatment for prolapse. Note that the distinction is based on treatment received, not on whether the women in the groups demonstrated prolapse. The panel desired to analyze the data based on whether or not patients had only stress incontinence or also evidenced prolapse. The data could not be analyzed in that manner since few studies stratified results in that manner. It was also not possible to find many groups of patients where all patients received prolapse treatment to enable a clean distinction between no prolapse treatment and those receiving incontinence treatment plus prolapse treatment.

Treatments

The panel considered a wide variety of treatments (see extraction form, appendix A4). As mentioned above, treatments shown to be less efficacious by the previous guideline were not extracted and analyzed (anterior repairs and trans-vaginal needle suspensions). However, limited data were available for many of the treatments of interest. In some articles, patients were treated by a variety of treatments but the outcomes weren't stratified by treatment. These articles were ultimately rejected.

Efficacy Analysis

The outcomes analyzed for efficacy included two levels of continence: cured/dry and cured/dry/improved. The first level includes patients reported as dry or totally cured. The second level also includes patients reported as improved. The percent of patients with each

condition were meta-analyzed. Credible intervals (Bayesian confidence intervals) were produced as well.

Urgency was also analyzed. Since not all patients had pre-operative urgency, an attempt was made to estimate urgency based on whether a patient had urgency prior to treatment. Patients were divided into three categories: 1) without pre-existing urgency, 2) with pre-existing urgency, and 3) unknown or uncertain pre-existing urgency. These categories are labeled 1) new onset, 2) pre-existing, and 3) unspecified in the outcomes tables. Urgency was further subdivided by type of post-operative urgency. The categories are 1) urge incontinence, 2) urge symptoms, and 3) unspecified for patients who have actual urge incontinence, urge symptoms alone, or unknown or unspecified urgency respectively. Again, the results are reported as the percent of the relevant patient group having each outcome.

The panel desired to estimate the impact of treatment on prolapse, both the resolution of existing prolapse and the development of new prolapse. However, the data extracted were insufficient to allow a meaningful analysis of these outcomes.

Complications

Different studies report complications grouped differently. They also use different names for similar complications. The panel grouped complications to try to include all similar complications. Only studies that specifically reported data concerning occurrences of complications were included in the analysis of complications. The panel did not assume that the lack of reporting implied the lack of occurrence of any specific complication. Although investigators may not have reported complications that did not occur, combining complications reduces the possibility of overestimating the complication rate. The probability that a patient will have a complication probably is still overstated slightly because some patients experience multiple complications. Thus, the result of the meta-analysis is best interpreted as the mean

number of complications the patient may experience rather than as the probability of having a complication. There were insufficient data to permit meaningful meta-analyses of patient deaths. The estimates of death rates provided in the guideline are the Panel's expert opinion based on the limited data available.

Retention was given special attention by the panel. A special section of the extraction form was dedicated to assessing retention and its duration. Unfortunately, there was some confusion during the extraction process. Retention data were not extracted in some cases where the follow-up for efficacy outcomes was less than 1 year. This was discovered too late in the process to go back and extract the additional data. In order to be consistent and avoid bias, data were only included in the analysis from studies with 1 year or greater follow-up. The panel examined the possibility of trying to estimate the probability of retention lasting various lengths of time. Insufficient data were available to analyze retention duration in any substantial way. The panel finally decided to estimate the probability that a patient had significant retention. Significant retention was defined as retention lasting 4 weeks or longer or retention requiring treatment (e.g. cutting a sling or otherwise modifying the original operation).

Guideline Generation and Approvals

After the evidence was combined and outcome tables were produced, the Panel met to review the results and identify anomalies. Additional teleconferences were held to review updates to the outcomes tables based on the problems identified. From the evidence in the outcome tables and expert opinion, the Panel drafted the treatment guideline. The draft was sent to 76 peer reviewers of whom 24 provided comments; the Panel revised the document based on the comments received. The guideline was submitted for approval first to the Practice Guidelines Committee of the AUA. Then it was forwarded to the Boards of Directors for final approval.

Dissemination

The guideline is published on the web site for the American Urological Association. A version of Chapter 1 will be published in the *Journal of Urology*.

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Chapter 3: Outcomes Analysis for the Surgical Management of Stress Urinary Incontinence

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Introduction

This chapter provides the results of the Panel's review of the literature and analysis, presented in outcomes tables, as well as discussions of the outcomes. Two sets of outcomes tables are provided including one set for patients who were treated only for stress incontinence and another set for patients who received treatment for both stress incontinence and some form of pelvic organ prolapse. Since some reports did not segregate patient data accordingly, for the purposes of this analysis if any patient in a group received concomitant prolapse surgery the entire group was included in the category.

Outcomes estimates are presented in two cells for each estimate; the first contains the number of groups of patients followed by the total number of patients (G/P) included in the meta-analysis. A group of patients usually represents the patients in a single study that the received indicated treatment(s). However, if a study had multiple groups with varying factors (e.g. degree of incontinence, details of the procedure used) these patients were analyzed as a separate group in the meta-analysis. In the second cell, the bolded percentage indicates the best estimate of the rate of occurrence of an outcome (median of the Bayesian posterior from the meta-analysis) followed by the 95% credible interval (Bayesian confidence interval) for that estimate. These numbers represent the best estimates that can be made from the existing data and served as the primary basis for the guideline statements presented in Chapter 1.

Efficacy Outcomes

Resolution of Stress Incontinence

The main efficacy outcome was the resolution of the stress incontinence. Cured and dry (cure/dry) was defined by the Panel as the complete resolution of symptoms with no residual leakage under normal and stress situations. Patients reported as having incomplete improvement were considered cure/dry/improved. There were inconsistencies in the reporting of these outcomes in the literature, with some authors distinguishing cured patients from improved patients and others reporting only those cured or improved/cured. The Panel accepted the author's representation (i.e. if a report indicated that a group of patients was cured they were counted as cured) but it is likely that not all patients counted in the cure/dry category were truly dry. If the author defined cured to include some degree of leakage, the patients were counted in the cure/dry/improved category only.

The outcomes were analyzed separately according to the method of incontinence assessment; the "subjective" outcome category included primarily patient reports and diaries and the "objective" outcome category included a variety of formal tests including urodynamics. A separate category ("any") was created for studies that didn't clearly specify how an outcome was assessed or for those using a mixed collection of measures. To make this "any" category complete, outcomes from all studies were included. If a study reported both subjective and objective outcomes, then the subjective outcomes were included in the "any" analysis. If a study reported outcomes from a variety of subjective measures, the one with the highest number of patients was used for both the subjective and "any" analyses.

The outcomes were analyzed by time of last assessment with the following intervals: 12–23 months, 24–47 months, and 48 months or more. If a study reported results for multiple times within one of these ranges, reports closest to 18, 36, and 60 months respectively were used. In this analysis, only studies that had a 12 month minimum follow-up were included; this is in contrast to the 1997 guideline¹ in which studies with a follow-up of less than 12 months were included if the minimum of the range was at least 12 months or the mean or average follow-up was at least 24 months.

Appendices A12-A16 show the results for patients who had no concomitant prolapse surgery for the time intervals 12–23 months, 24–47 months, and greater than 48 months, respectively. Appendices A7 – A11 are arranged similarly and show data for patient groups in which some or all of the patients had concomitant prolapse treatment. Treatments with no available data in are excluded from the tables; thus, not all treatments are presented in all tables.

Urgency

The Panel recognizes the importance of the relationship between surgery for SUI, the complaint of involuntary leakage on effort, exertion, sneezing or coughing (as defined by the International Continence Society [ICS])² or with physical exertion (as defined by the National Institutes of Health)³ and other lower urinary tract symptoms (LUTS; defined as storage, voiding, and postmicturition symptoms by the ICS). OAB syndrome is comprised of the main storage symptoms of LUTS and is defined by the ICS as urgency (the complaint of a sudden, compelling desire to pass urine which is difficult to defer or a strong need to pass urine for fear of leakage (NIH), with or without urgency urinary

incontinence (UUI; involuntary leakage accompanied by or immediately preceded by urgency), usually with frequency and nocturia, in the absence of pathologic or metabolic factors that would explain these symptoms.²

The Panel accepted the author's use of "urge", "urge incontinence" or "urgency" with or without "incontinence" without requiring specific adherence to these definitions. The Panel attempted to distinguish those patients having urge incontinence from those having symptoms of urgency alone in the absence of urge incontinence. However, this distinction was not always reported. Three categories of studies were analyzed: 1) those that included patients with urge incontinence alone; 2) those that included patients with urgency symptoms alone; and 3) those that included patients with unspecified urgency or that combined patients with incontinence and urgency symptoms. Because urgency can occur with stress incontinence and is often resolved with treatment of stress incontinence, the data for urgency are listed in the efficacy section of this chapter; however, urgency occurring de novo after incontinence surgery could also be considered a complication of the treatment. A third category was analyzed for studies not reporting the preoperative urgency status of patients with postoperative urgency and those in which patients with and without preoperative urgency were combined.

Appendix A15 provides the results of the Panel's analyses of urge incontinence, urgency symptoms alone, and unspecified urgency for patients who did not receive concomitant prolapse surgery. Appendix A10 provides the same outcomes in the group of patients where some or all had concurrent prolapse repair. Each table contains three data sets corresponding to 1) continuing urgency in patients with pre-existing urgency; 2) de

novo urgency in patients who did not have preoperative urgency, and 3) unspecified or mixed cases. The format of each entry is the same as for stress incontinence resolution.

The success of surgery for decreased outlet resistance is intimately related to preoperative and postoperative storage and emptying function. The interrelationship of the individual symptoms comprising LUTS (storage and emptying), OAB or urgency/urgency incontinence and of the LUTS to the results of surgery is complex. Patients with SUI may experience no other LUTS or may develop one or more symptoms postoperatively. Alternatively, patients with one or more preoperative LUTS may have symptoms that independently improve, persist, or worsen. In addition, the de novo development, improvement or worsening of symptoms may be acute (temporary) or chronic (permanent). These symptoms may also increase (aging of population, comorbidities) or decrease (resolution of perioperative alterations) over time.

The Panel recognizes the symptoms of “urgency” and “urgency urinary incontinence” as the most commonly reported and most representative of pre-existing or de novo lower urinary tract storage symptoms. Although preoperative cystometry was performed in some studies, postoperative urodynamics were rarely performed in patients regardless of symptoms; thus, patient results are almost universally reported based on symptoms. It is recognized that the symptoms of urgency or UUI may or may not correlate with the urodynamic (cystometric) finding of detrusor overactivity. Additionally, patients may experience detrusor overactivity that is provoked by effort or exertion, or may experience detrusor overactivity without sensation, further confounding the diagnosis and therapy.

Table 1 provides data on patients experiencing postoperative urgency or urge incontinence from the 1997 review¹ and from the current analysis, although these data aren't directly comparable in that the 1997 analysis examined the correlations between urgency and detrusor instability. As mentioned above, the present analysis focused on the development of de novo urgency and urge incontinence and separately analyzed the resolution of these symptoms patients with the presence of urgency and urge incontinence.

OAB is common in women with SUI, occurring in 30%–50% of cases⁴, with surgical treatment of SUI often offering resolution of OAB.^{5,6} Unfortunately, persistence of OAB after SUI surgery has been reported in up to 40% of patients.^{7,8} Persistent OAB has been reported to complicate 8%–25% of all sling procedures,⁹ as well as 7.6%–12% of TVT procedures and 1.4%–16.6% of retropubic urethropexies.¹⁰⁻¹² In the present analysis, persistence of urgency occurred in approximately 15% of those receiving suspension procedures and about 30% of those receiving sling procedures. Moreover in 7%–21% of cases, de novo OAB may occur.^{7,13-16} Possible risk factors for de novo OAB include undiagnosed preoperative OAB, increased bladder wall thickness (induced by or associated with resultant changes in bladder afferent and/or efferent neuromuscular behavior), bladder neck dissection, greater patient age, and postoperative urethral obstruction.¹⁴

Complications

Complications were analyzed similarly to the efficacy outcomes. Because of the wide variation in terms used to describe complications, the Panel grouped complications

together that represented similar or related outcomes (See Appendix A17 for complications groupings). As discussed in Chapter 2, this could result in some inaccuracies in the resultant estimates. Outcomes tables were developed for each group of complications, with separate tables created for the population of patients receiving or not receiving concurrent prolapse treatment. The format of the tables is the same as for the efficacy tables, but the layout is reversed. The treatments are across the top for complications and down the left side for the others.

Retention

The Panel defined retention as catheter-dependency for greater than 28 days postoperatively and/or the need to undergo an intervention to correct retention following surgery. Using these definitions, retention estimates ranged from 1%–9% in the population without prolapse treatment and from 1%–10% in the population with concurrent prolapse treatment (Appendices A9 and A14). As a group, those undergoing retropubic procedures had retention estimates of 4% for the non-prolapse group and 1% for the prolapse group. Patients undergoing sling procedures were more likely to experience retention with the highest rates observed in those undergoing synthetic slings at the bladder neck without bone anchors. In these groups, the estimates were 9% and 10% for the non-prolapse treatment and the prolapse treatment populations, respectively. The lack of a standardized definition of retention and the failure of many studies to provide data regarding postoperative urinary retention were limitations to this analysis. Yet, from the present analysis it may be concluded that retention affects 1%–10% of

women postsurgically and varies by procedure, with sling procedures having higher rates of retention than retropubic procedures.

Genitourinary Complications

With regard to genitourinary complications, the Panel analyzed these events as intraoperative complications (events occurring during the surgical procedure or in the immediate perioperative period) or other complications (events occurring after the immediate perioperative period). The purpose of this distinction was to identify complications that may be unique to the technical aspects of a particular procedure or complications that may be related to the consequences of or materials utilized in the procedure.

Intraoperative complications

Bladder injury was reported with 3%–8% of procedures (Appendices A11 and A16).

Although the overall incidence was low, it appeared that bladder injury was more frequent in patients receiving SUI procedures with concomitant prolapse repair. This trend may be the result of the more extensive dissection needed when doing a simultaneous prolapse repair, however the trend did not reach significance and therefore may be not representative of actual experience as well. In addition, the risk of bladder injury was somewhat higher (not statistically significant) in procedures utilizing synthetic materials at the midurethra, particularly when compared to autologous slings and retropubic suspensions. This finding may have been a result of more stringent data recording in the use of synthetic materials or possibly related to technical aspects of

certain midurethral slings. Trocar placement into the retropubic space in the absence of advanced mobilization of the bladder and urethra may predispose to a higher incidence of bladder and urethral injury. Urethral injury was only identified in association with synthetic slings placed at the midurethra or laparoscopic retropubic suspensions. This may be related to technical aspects of the midurethral sling procedure that may predispose to these types of injuries. However, the small cohort of patients did not allow a direct comparison with other procedures. Ureteral injuries occurred during less than 5% of the procedures in most series; however, they were reported in 4%–11% of laparoscopic suspensions, which seemed to the Panel to be higher than expected based on their experience. Many of the reported cases of laparoscopic suspensions reflected the early experiences of surgeons and perhaps this could explain the increased risk of laparoscopic suspensions when compared with other procedures.

Other complications

With the many different techniques and materials utilized in the surgical correction of SUI, surgeons must remain diligent in obtaining long-term outcomes data to understand the effects of these techniques and materials on quality-of-life and potential complications. Of major contemporary concern is the resurgence of the use of mesh materials in the surgical correction of SUI, particularly with the recent emergence of the tension-free midurethral sling procedures using synthetic materials. Early experience with synthetic mesh materials in pubovaginal sling and prolapse surgeries was associated with a considerable risk of mesh complications. Erosion rates of 20%–30% were reported in patients following implantation of Dacron™, Mersilene™, and Marlex™ mesh

materials.¹⁷⁻¹⁹ In these early procedures, larger incisions with more extensive dissection may have increased the potential for bacterial exposure, and increased tension may have promoted tissue ischemia. The woven, multifilamentous nature of these mesh materials may have limited the ingrowth of host tissue, leading to erosions, draining sinuses, and fistulas. These early experiences forced many surgeons to abandon the use of synthetic material in pelvic reconstructive surgery.

The success of the TVT procedure introduced surgeons to several principles that have seemingly facilitated the safe use of synthetic material in pelvic reconstruction. The use of small incisions and minimal dissection decreases the potential for bacterial exposure. The avoidance of tension on the mesh material limits local tissue ischemia while the use of macroporous monofilament mesh materials promotes host tissue ingrowth and biocompatibility. Incorporating these principles, the synthetic tension-free slings have become one of the more commonly used procedures in the surgical management of SUI. The reported incidence of mesh erosions and complications with these procedures appears quite low, although the true incidence is not known. A recent report analyzing the United States Food and Drug Administration Manufacturer and User Facility Device Experience database (U.S. FDA MAUDE)²⁰ which collects data on U.S. FDA approved medical devices, suggests that these complications are indeed underreported.²¹ In addition to mesh materials, permanent suture materials, tacking devices and laparoscopic instrumentation may also be associated with lower urinary tract or vaginal injuries.

Erosions and extrusions may also occur with the use of foreign materials such as mesh. For the purposes of this review, the Panel has defined erosion as the presence of a

foreign body in the lumen of the urinary tract (bladder, urethra or ureter) whereas extrusion was defined as the exposure of mesh in the vagina. Urinary tract erosion has been reported subsequent to all SUI procedures, but overall this does not appear to be a common event. In this meta-analysis (Appendices A11 and A16), erosion into the urethra and bladder occurred following 2%–4% of vaginal sling procedures. Erosions appear to occur more frequently following synthetic sling procedures; however, the method of reporting varies widely. Some authors have reported that “erosions” occurred but were not specific as to location and type. For example, 17% of erosions resulting from synthetic slings placed at the bladder neck were not classified. The incidence of urethral and bladder erosions appears to be higher following placement of synthetic slings at the bladder neck when compared to autologous slings. These data might suggest that synthetic slings have a higher rate of erosion than autologous or cadaveric slings. Based on these findings, the Panel believes that discussion of urinary tract erosion should be part of the informed consent process, particularly when selecting synthetic slings. The Panel also concludes that urinary tract erosion is a risk of any surgical procedure used in the treatment of SUI, with the risk appearing highest for synthetic slings, particularly when placed at the bladder neck.

Vaginal extrusion occurred in 1-8% of cases following synthetic slings. In this meta-analysis, the unexpectedly high risk of vaginal extrusion associated with cadaveric slings (23%) probably represents an anomaly resulting from the fact that few studies of cadaveric slings mentioned extrusion and the one study reporting this complication was small. Since the small number of series may affect the overall data reporting and incidence rates, this result is likely artifactual.

General Medical Complications

General medical complications captured in this analysis included cardiovascular, dermatologic, febrile, infectious (local, systemic, and urinary tract), neurologic, and pulmonary complications as well as subjective complications such as pain and sexual dysfunction (Appendices A11 and A16). In addition, transfusion was analyzed as a separate category. There was variable and limited reporting of most general medical complications, with many authors not reporting any complications data. These findings reinforce the need for standardized reporting of complications, particularly as related to general medical complications.

Urinary tract infections were the most commonly reported infectious complication, with estimates following retropubic surgery of 13% for those not undergoing concurrent prolapse procedures and 17% for those receiving such procedures. Patients undergoing sling procedures were less likely to experience urinary tract infection, with estimates of 4%–16% for the no prolapse treatment groups and 1%–9% for the prolapse-treatment group. However, the majority of authors did not report specifically on the presence or absence of urinary tract infections and caution must be used in interpreting these data.

There was very little uniformity in reporting other infectious complications. Febrile morbidity estimates were between 0%–14% of patients depending upon the procedure. The highest estimates were noted in the retropubic groups with rates of 8%–11% for the non-prolapse and prolapse treatment groups, respectively. Patients undergoing sling procedures were less likely to have a febrile morbidity reported and this

was true for both treatment groups. The reported estimates of febrile morbidity ranged in those populations between 2%–8%.

Dermatologic complications were reported only in patients receiving injectable collagen, with an estimate of 5%. The estimates for sexual dysfunction were 4% for retropubic suspensions and 8% for autologous fascial slings. However, the definitions and reporting methods for identifying sexual dysfunction remain extremely variable in the evidence as assessed. Therefore the rates reported may not be representative of the true incidence of this outcome. Standardization of reporting indices is critically needed for a better understanding of the true rates of sexual dysfunction arising from interventions for stress incontinence and pelvic organ prolapse.

Operative Complications

Gastrointestinal complications

All procedures performed adjacent to the peritoneal lining and its contents are associated with risks of injury to the bowel and such injuries have been reported with open, laparoscopic and “minimally invasive” procedures. “Minimally invasive” synthetic-based retropubic procedures had the highest reported risk of bowel complications, with estimates of 1% for synthetic midurethral slings performed without concomitant prolapse repair (see Appendix A16). There were too few reports of bowel injuries resulting from the other procedures for a meaningful comparison.

Vascular complications

Vascular complications were defined as any reported iatrogenic intraoperative injury to a specific major or significant blood vessel not including intraoperative or postoperative bleeding or hematomas. The estimates for vascular complications are found in Appendices A11 and A16. There were no reported vascular complications in over 400 articles reviewed for this meta-analysis involving an anti-incontinence procedure with or without pelvic organ prolapse repair in approximately 40,000 patients. Yet, it is well known that major vascular injuries including iliac, femoral, obturator, and epigastric vessel injury have been reported with the TVT procedure in the FDA MAUDE database.²⁰ The Panel believes that the risk of serious vascular complications with TVT procedures is very low; but nevertheless surgeons should bear this risk in mind when performing this technique.

Neurologic complications

Neurologic complications occurring in association with SUI surgery are rare (see Appendices A11 and A16). A total of five cerebrovascular accidents (CVA) were reported. CVA occurred more frequently in patients undergoing retropubic suspensions (n=3) versus pubovaginal slings (n=1) or midurethral slings (n=1), although the small numbers of these events preclude statistical analysis. No patient required additional surgery as a result of a CVA but CVA was the cause of death in three patients. While all of the CVAs may be attributable to the patient having had an anesthetic and/or surgery, one must take into consideration the age and other comorbidities of patients who elect surgical correction of SUI.

Twelve nerve injuries were reported. In some cases these were listed only as “nerve injury” whereas in other reports they were described by the resulting deficit or as an injury to a discrete nerve. The most common nerve injury cited was to the obturator nerve, which occurred in three patients. There were nerve injuries described with the use of midurethral synthetic slings (n=5); however, none of these patients required additional surgical procedures. Two patients required additional surgical procedures to treat complications related to nerve entrapment. One patient had removal of a suture and a second patient underwent removal of a bone anchor using a hammer and osteotome.

Infectious complications

The panel elected to divide infectious complications into multiple subsets to accommodate the various definitions presented in the literature; these included infection (undefined), infection with local extension, abscess, and osteomyelitis (see Appendices A11 and A16). Osteomyelitis, rarely reported, was observed in procedures with and without bone anchors.

Death

The risk of perioperative mortality following surgical treatment of SUI is very low, although a precise estimate is difficult to achieve due to the paucity of studies that specifically evaluate mortality, compounded by the fact that published studies represent only a tiny fraction of all surgical procedures performed. To gain an estimate of perioperative mortality in the SUI patient population, a combined approach was taken: 1) the raw data from the current analysis were assessed; 2) a Medline search was performed

using the term “perioperative mortality” and reports were obtained for all surgical procedures in the U.S. and also for surgical procedures thought to be of comparable risk to SUI surgery; and 3) reports were obtained that specifically dealt with surgical procedures for SUI and urogynecology (shown in Table 2²²⁻²⁹). Finally, an estimate was determined for the added perioperative mortality from the special circumstances of vascular or bowel injury due passage of trocars from midurethral sling kits.

In contemporary series, overall perioperative mortality for all surgical procedures ranged from 0.02%–1.8% (Table 2). In the Medline search on which this review was based, there were three deaths out of 39,019 patients, for a mortality rate of 0.008%. Waetjen et al²⁶ reported an unadjusted mortality rate of 0.01% in a survey of 135,000 women undergoing incontinence surgery in the U.S. in 1998. However, in that series pubovaginal slings accounted for less than 15% of the procedures; nearly three-quarters had either retropubic suspension or anterior repair. This is probably an underestimation of mortality due to bowel or vascular injury from trocars. No other reports that dealt specifically with mortality after incontinence surgery were identified. Sung et al²⁹ reported an unadjusted risk of death following all urogynecologic procedures of 0.04% and noted that mortality rate increased with age. For women less than 60 years of age, the mortality rate was 0.01%; for those more than 80 years of age it rose to 0.28%. The authors noted that elderly women had a 13-fold increase in the risk of death and a 33% higher risk of suffering postoperative complications compared with younger women, irrespective of their co-morbidities.²⁹ Brown et al²⁷ reported a perioperative mortality of 0.03% after pelvic organ prolapse surgery. In a study of surgical mortality, Pine et al²⁸ reported mortality rates for various surgical procedures. The Panel selected those that

were the most comparable to incontinence surgery for a comparison of perioperative mortality data. The unadjusted mortality rates were 0.11%, 0.41% and 0.20% for hysterectomy, herniorrhaphy, and prostatectomy, respectively (Table 2).

Finally, the Panel estimated the minimal mortality after the TVT procedure by accessing the US FDA MAUDE Database²⁰ (now known as MedWatch) using the terms “TVT,” “transvaginal tape,” “sling,” “pubovaginal sling,” and “suburethral sling” which yielded incident reports that included six deaths. Three of the deaths were associated with bowel perforations and one each resulted from hemorrhage, myocardial infarction and pulmonary embolism. In addition, Panel members have documented at least two other deaths due to vascular injury.

In summary, perioperative mortality after sling surgery in the index patient is low; the Panel estimates it at between 0.01%–0.09%. However, mortality increases with advancing age and comorbidities, with mortality nearly three per 10,000 in patients over 80 years of age. Blind passage of trocars into the retropubic space potentially increases the possibility of bowel or vascular injury that could lead to mortality.

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1 **Table 1. Patients experiencing postoperative urgency or**
 2 **urge incontinence**

	Retropubic Suspensions		Transvaginal Suspensions		Sling Procedures	
	G/P	Median CI (2.5-97.5%)	G/P	Median CI (2.5-97.5%)	G/P	Median CI (2.5-97.5%)
<i>Prior Analysis¹</i>						
Urgency						
+ urgency/+DI*	6/78	66 (50–79)	6/33	54 (35–73)	4/45	46 (24–68)
+ urgency/–DI*	6/319	36 (22–52)			5/110	34 (13–61)
– urgency/+DI*	1/6	4 (0–33)	1/3	7 (0–54)	4/36	20 (5–45)
– urgency/–DI*	8/241	11 (8–16)	6/150	5 (3–10)	7/140	7 (3–11)
<i>Current Analysis</i>						
Urge Urinary Incontinence						
New Onset		10-14				11-22
Pre-existing		22-48				29-52
Urgency						
New Onset		9-11				13 (Grade>1)
Pre-existing		40 (Grade<1)				21 (Grade>1)

3 * Preoperative status

4 Abbreviations: CI, confidence interval; DI, detrusor instability; G/P, number of groups and number of
 5 patients per treatment arm

1 **Table 2. Estimated perioperative mortality for SUI and**
2 **urogynecologic surgical procedures**

3

Surgical procedure	Mortality rate
Overall perioperative mortality ^{22-25,28}	0.02 – 1.8%
Stress incontinence ²⁶	0.01%
Urogynecology ²⁹	0.04%
< 60 years	0.01%
61 – 69 years	0.05%
70 – 79 years	0.09%
> 80 years	0.28%
Hysterectomy ²⁸	0.11%
Pelvic organ prolapse ²⁷	0.03%
Herniorraphy ²⁸	0.41%
Prostatectomy ²⁸	0.20%

4

Appendix A1: Female Stress Urinary Incontinence Clinical Guidelines Panel, Consultants and Data Extractors (1997)

Members:

Gary E. Leach, MD (Panel Chair)
University of California, Los Angeles
Los Angeles, CA

Roger R. Dmochowski, MD (Panel Facilitator)
University of Tennessee Medical Center
Memphis, TN

Rodney A. Appell, MD
Cleveland Clinic Foundation
Cleveland, OH

Jerry G. Blaivas, MD
New York Hospital/Cornell Medical Center
New York, New York

H. Roger Hadley, MD
Loma Linda University Medical Center
Loma Linda, CA

Karl M. Luber, MD
Southern California Permanente Medical Group
San Diego, CA

Jacek L. Mostwin, MD
Johns Hopkins Hospital
Baltimore, MD

Pat D. O'Donnell, MD
University of Arkansas
Fayetteville, AR

Consultants:

Claus G. Roehrborn, MD
Hanan S. Bell, PhD
Patrick M. Florer
Curtis Colby

Data Extraction:

Jeffrey Csiszar, MD
Jill Gerspach, MD
Steven Kurtz, MD
Susan Martins-Levy, MD
Hetal Patel, MD
Lisa Stout, MD

Appendix A2: Female Stress Urinary Incontinence Guideline Update Panel and Consultants (2009)

Members:

Rodney A. Appell, MD (Chair)
Baylor College of Medicine
Houston, TX

Roger R. Dmochowski, MD (Facilitator)
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Saad Juma, MD
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Eric Scott Rovner, MD
Medical University of South Carolina
Charleston, SC

Jerry G. Blaivas, MD
New York, New York

Consultants:

Hanan Bell, PhD

Linda E. Whetter, PhD, DVM

Patrick Florer

Kirsten H. Aquino

Appendix A3 - Article Staus Report
American Urological Association, Inc.
SUI Guidelines Update Panel

November-09

Literature Search	Articles Retreived	Selected for Extraction	% of Lit Search / Total
Original Guideline	1,069	101	9%
December, 2002	4,943	942	19%
May, 2004	787	162	21%
December, 2004	134	60	45%
Jun, 2005	176	37	21%
	7,109	1,302	18%

Data Entry	Articles	% Selected for Extraction
Entered	1,302	100%
in Process	0	0%
	1,302	100%

Article Status	Articles	% Data Entered
Accepted	436	33%
CX data only	155	12%
Rejected	866	67%

Reasons for Rejection	Articles	% Total Rejected
No Data	292	34%
Insufficient Efficacy F/U	282	33%
RX not Current	124	14%
Not about RX	100	12%
Basic Science	12	1%
Epidemiology	4	0%
Other	40	5%
Prolapse only	40	5%
Other Exclusion	264	30%
Duplicates	5	1%
Panel Rejects	0	0%

Analysis of Study Designs	Articles	Overall Number of Patients
Accepted Articles		
Case Series/Report	373	30,166
unknown at this time	16	4,295
Controlled Trial	31	2,833
Case-control study	9	1,061
Cohort Study	5	449
Opinion or Testimony	1	154
Letter	1	61
Total:	436	39,019

Rejected Articles	Articles
not captured	730
Case Series/Report	75
Review/Policy	26
Letter	16
Opinion or Testimony	6
Controlled Trial	4
Meta-analysis	4
Other	2
Case-control study	1
Cohort Study	1
Database or Surveillance	1
Total:	866

Appendix A4- Extraction Form

American Urological Association, Inc.

Reference # _____

SUI Guidelines Panel

Stress Urinary Incontinence Cover Sheets

Citation:

Extractor A: _____ Date: _____

Extractor B: _____ Date: _____

Reconciliation Date: _____

ACCEPTED and Extracted

___ Insufficient treatment efficacy follow-up
 ___ Complications data only extracted

___ Needs Panel Review

1. Study Design

___ Case Series/Report
 ___ Controlled trial
 ___ Review/policy
 ___ Case-control study
 ___ Cohort Study
 ___ Meta-analysis
 ___ Data base or surveillance
 ___ Letter: Ref. _____
 ___ Opinion or testimony
 ___ Other: spec. _____

2. Are there particular difficulties with this study that make it less useful for our purposes (include study flaws and items that cause the study interventions or population not to match our needs)?

___ Serious design flaws (specify _____)
 ___ Randomization failure
 ___ Confounders present
 ___ Selection bias
 ___ Patient population not relevant
 ___ Incomplete or biased statistics/data
 ___ Blinding failure or insufficient
 ___ Compliance problems (intensity)
 ___ Cross-over problems
 ___ Atypical intervention

Other: (describe)

REJECTED and not Extracted

Article REJECTED due to (check all that apply):

___ No relevant outcomes or complications data
 ___ Insufficient treatment efficacy follow-up (must be > 12 months)
 ___ Treatments not current (Stamey, etc.)
 ___ Doesn't deal with treatment:
 ___ Basic Science ___ Epidemiology ___ Other
 ___ Purely Prolapse paper
 ___ Other reason for exclusion:
 specify: _____

Study Features (check all that apply)

___ Retrospective
 ___ Prospective
 ___ Randomized
 ___ Patient blinded
 ___ Provider blinded
 ___ Outcome evaluator blinded
 ___ Cross-over

3. Are there other data or points in this article that would be relevant that are not covered elsewhere?

Appendix A4- Extraction Form

American Urological Association, Inc.

Reference # _____

SUI Guidelines Panel

Stress Urinary Incontinence Cover Sheets

4. Study: Total Patients enrolled: _____ (N)
Country: _____ Check if multi-center/location
Study Dates: _____ through _____ (leave blank if not specified)

5. Group Definitions:

Group ID	Patients	Definition

6. Comments:

7. Total time completing this extraction: _____ minutes.

American Urological Association, Inc.

Reference # _____

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence

Group Characteristics

8. Group Characteristics

Patients: N = _____

Age:

Mean: _____

Med: _____

Min: _____

Max: _____

9. Coexistent Conditions

	Check	%	Num	Comments/Definition
Cystocele B-W I				
II				
III				
IV				
Cystocele unspecified				
Rectocele				
Enterocoele				
Uterine Prolapse				
Vaginal Vault Prolapse				
Neurogenic Bladder				
Urethrovaginal Fistula				
Urethral Diverticulum				
Other				
Other				

10. Other Patient Characteristics

	Check	%	Num	Comments/Definition
Pts. With Prior Incont. Surgery				
Mean Procedures/Pt.				
Hyst Unspecified				
Vag Hyst				
TAH				
TAH+BSO				
TV BNS				
RP BNS				
Previous Prolapse Repair - unspecified				
Cystocele - unspecified				
A. Anterior Repair				
B. Paravaginal Repair				
Rectocele				
Enterocoele				
Uterine Prolapse				
Vault Prolapse				
Pts. With prior Surgery (notspec.)				
Parity: Parous				
Mean Parity				
Min Parity				
Max Parity				
Mean Deliveries/Pt.				
Nulliparous				

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence**Group Characteristics****10. Other Patient Characteristics (cont.)**

	Check	%	Num	Comments/Definition
Obesity				
Pre-Menopausal				
With Estrogen				
Post-Menopausal				
With Estrogen				

11. Methods of Evaluation

Subjective	Check	%	Num	Comments/Definition
Pt. Interview				
Voiding Diary/Log				
MD Perception				
Chart Review				
Rating Form				
QOL Rating				
Analog Scale				
Questionnaire				
Other				
Unspecified				

Objective	Check	%	Num	Comments/Definition
Physical Exam				
Stress Test				
BN Evaluation				
Q-tip				
Pad Test				
Pads/Diapers				
Baden-Walker				
POP-Q				
VCUG				
Urodynamics				
Video-Urodynamics				
Barrier Testing				
Other				

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence**Group Characteristics****12. Diagnostic Findings**☐ Symptoms only☐ Stress test☐ Urodynamics

	Check	%	Num	Comments/Definition
SUI				
ISD				

SUI				
ISD				

Grade	Check	%	Num	Comments/Definition
Mild				
Mod				
Severe				

Mild				
Mod				
Severe				

	Mean	Median	Min	Max	Check	%	Num	Comments/Definition
Pads								
Diapers								

Pads								
Diapers								

	Check	%	Num	Comments/Definition
Urodynamically proven motor DO				
Urgency symptoms				
Mixed (SUI/motor DO or Urgency)				

Urodynamically proven motor DO				
Urgency symptoms				
Mixed (SUI/motor DO or Urgency)				

13. Comments on Group Characteristics

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence

Treatments

14. Treatments

SUI handled before or after Prolapse repair or sling: before / after (circle one)

A. Treatments for Incontinence
Suspensions

	Check	%	Num	Comments/Definition
Open Retropubic Suspensions				
Laparoscopic Suspension				
Transvaginal Cooper's Ligament Suspension				
Burch Suspension				
Other Suspensions (specify)				

Slings

	Check	%	Num	Comments/Definition
Autologous fascia w/o bone anchors				
Autologous fascia with bone anchors				
transvaginal				
suprapubic				
Autologous vaginal wall slings w/o bone anchors				
Autologous vaginal wall slings with bone anchors				
transvaginal				
suprapubic				
Cadaveric w/o bone anchors				
Cadaveric with bone anchors				
transvaginal				
suprapubic				
Xenograft w/o bone anchors				
Xenograft with bone anchors				
transvaginal				
suprapubic				
Synthetic at bladder neck w/o bone anchors				
Synthetic at bladder neck with bone anchors				
transvaginal				
suprapubic				
Synthetic at midurethra				
Homologous tissue (dermis) w/o bone anchors				
Homologous tissue (dermis) with bone anchors				
transvaginal				
suprapubic				
Cooper's ligament sling (all sling materials)				
Other Sling (specify)				

Check % Num Comments/Definition

Artificial Sphincter

--	--	--	--	--

Injectables

	Check	%	Num	Comments/Definition
Collagen				
Other degradable materials				
Other non-degradable synthetics				
Other Injectables (specify)				

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence

Treatments

14B. Treatments for Prolapse

Anterior compartment repairs

	Check	%	Num	Comments/Definition
Plication (colporrhaphy)				
Paravaginal				
Abdominal approach				
Vaginal approach				
Interposition graft				
Combination (specify)				
Other (specify)				
Not Stated				

Apical Repair

	Check	%	Num	Comments/Definition
McCall Procedure				
Uterosacral Suspension (plication)				
Levator myorrhaphy				
Iliococcygeus repair				
Sacrocolpopexy				
Sacrospinous fixation				
Other (specify)				
Not Stated				

Posterior Compartment Repairs

	Check	%	Num	Comments/Definition
Site specific				
Plication				
Interposition graft				
Combination repair				
Other (specify)				
Not Stated				

Enterocoele repair

	Check	%	Num	Comments/Definition
Culdoplasty (specify)				
Plication				
Other, Transvaginal Repair				
Other, Abdominal Repair				

C. Other Treatments

	Check	%	Num	Comments/Definition
Abdominal hysterectomy				
Vaginal hysterectomy				

15. Comments about treatments for this group:

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence

Group Outcomes

16. Patients w. Follow-up: N= _____ Mean: _____ Median: _____ Min: _____ Max: _____
 Follow-up (mo): _____

17. Outcome Assessment Tools:

Subjective	Check	%	Num	Comments/Definition of Success/Failure
Pt. Interview				
Voiding Diary/Log				
MD Perception				
Chart Review				
Rating Form				
QOL Rating				
Analog Scale				
Questionnaire				
Other				
Unspecified				

Objective	Check	%	Num	Comments/ Definition of Success/Failure
Physical Exam				
Stress Test				
BN Evaluation				
Q-tip				
Pad Test				
Pads/Diapers				
Baden-Walker				
POP-Q				
VCUG				
Urodynamics				
Video-Urodynamics				
Barrier Testing				
Other				

18. Outcomes in Regard to Continence Status only

1 st	Subj	Obj	%	Num	Denom	Comments\Definition
_____ Months		Cure/Dry				
_____ Mean Mos		Improved				
_____ Median Mos		Failure				
_____ Min Mos		Retreatment				
_____ Max Mos						
_____ SE Mos						
_____ STDev Mos						
_____ % CI, _____ to _____ Mos						

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence

Group Outcomes

18. Outcomes in Regard to Continence Status only (cont.)

2 nd	Subj	Obj	%	Num	Denom	Comments\Definition
_____ Months		Cure/Dry				
_____ Mean Mos		Improved				
_____ Median Mos		Failure				
_____ Min Mos		Retreatment				
_____ Max Mos						
_____ SE Mos						
_____ STDev Mos						
_____ % CI, _____ to _____ Mos						

3 rd	Subj	Obj	%	Num	Denom	Comments\Definition
_____ Months		Cure/Dry				
_____ Mean Mos		Improved				
_____ Median Mos		Failure				
_____ Min Mos		Retreatment				
_____ Max Mos						
_____ SE Mos						
_____ STDev Mos						
_____ % CI, _____ to _____ Mos						

19. Management of Bladder:

Method of Bladder Drainage	Check	%	Num	Denom	Comments\Definition
Foley Catheter					
Suprapubic Catheter					
Self Catheterization					

Author's Definition of Retention: _____

Patients in Retention	@Days	%	Num	Denom	Comments\Definition
_____ @ Discharge					

Days in Retention	Mean	Median	Min	Max	SE	STDev	%CI

Secondary Procedures for Patients in Retention	@ Mo	Num	Prev.
1.			
2.			
3.			
4.			

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence**Group Outcomes****20. Complications (Peri-operative and during Follow-Up)**

	Time	Check	%	Num	Denom	Comments\Definition
None (per Author)						
Transfusion						
Acute Bleeding						
Hematoma						
Death						
Infection						
Local Extension						
Systemic						
Wound						
UTI						
Wound						
Vaginal						
Major						
Minor						
Abdominal						
Major						
Minor						
Removal of For. Body- other						
Stitches						
Pledget						
PE/DVT						
MI						
CVA						
Pulmonary						
Bladder Injury						
Bowel Injury						
Vascular Injury						
Rectal Injury						
Fistula						
Dysuria						
Sexual Dysfunction						
Urethral Erosion						
Other Complications						
Other Complications						
Other Complications						
Other Complications						

21. Bleeding

Mean: _____ Median: _____ Min: _____ Max: _____

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence

Group Outcomes

22. Urgency and Urge Incontinence

	Time	Check	%	Num	Denom	Comments\Definition
Urge Incontinence – New onset						
Pre-existing						
Unspecified						
Urgency symptoms – New onset						
Pre-existing						
Unspecified						
Unspecified urgency–New onset						
Pre-existing						
Unspecified						

23. Prolapse Outcomes

A. Cystocele

	Time	Check	%	Num	Denom	Comments\Definition
Recurrence						
Failure						
New Prolapse						
Post-op (unspecified)						
Other (specify)						

B. Rectocele

	Time	Check	%	Num	Denom	Comments\Definition
Recurrence						
Failure						
New Prolapse						
Post-op (unspecified)						
Other (specify)						

C. Enterocele

	Time	Check	%	Num	Denom	Comments\Definition
Recurrence						
Failure						
New Prolapse						
Post-op (unspecified)						
Other (specify)						

D. Uterine Prolapse

	Time	Check	%	Num	Denom	Comments\Definition
Recurrence						
Failure						
New Prolapse						
Post-op (unspecified)						
Other (specify)						

SUI Guidelines Panel

Group Number: _____

Stress Urinary Incontinence**Group Outcomes****E. Vault Prolapse**

	Time	Check	%	Num	Denom	Comments\Definition
Recurrence						
Failure						
New Prolapse						
Post-op (unspecified)						
Other (specify)						

F. Other/unspecified/total (_____)

	Time	Check	%	Num	Denom	Comments\Definition
Recurrence						
Failure						
New Prolapse						
Post-op (unspecified)						
Other (specify)						

24. Comments (regarding this group only)

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7109 articles listed

SUI Guideline Update Panel

Efficacy - Cure / Dry
ANY Prolapse*

Suspensions	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
All Open Retropubic	7/460	89% (84 - 93)%	2/35	86% (69 - 96)%	9/517	88% (83 - 92)%
Burch	7/460	89% (84 - 93)%	2/35	86% (69 - 96)%	9/517	88% (83 - 92)%
Laparoscopic	3/150	87% (75 - 94)%	4/146	87% (81 - 92)%	12/564	88% (85 - 91)%

Slings	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Autologous fascia without bone anchors	1/36	89% (76 - 96)%	2/42	97% (87 - 100)%	3/78	92% (82 - 97)%
Autologous vaginal wall slings w/without bone anchors					1/20	70% (48 - 86)%
Autologous vaginal wall slings with bone anchors - Suprapubic					1/19	99% (88 - 100)%
Cadaveric with bone anchors - Transvaginal	1/234	82% (77 - 86)%			1/234	82% (77 - 86)%
Cadaveric without bone anchors	3/133	58% (36 - 78)%			3/133	58% (36 - 78)%
Homologous tissue (dermis) without bone anchors						
Synthetic at bladder neck with bone anchors - Suprapubic						
Synthetic at bladder neck with bone anchors - Transvaginal						
Synthetic at bladder neck without bone anchors						
Synthetic at midurethra	8/647	85% (80 - 89)%	8/489	86% (77 - 93)%	14/1089	85% (80 - 89)%
Other Sling					1/126	92% (86 - 96)%

Injectables	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Other non-degradable synthetics						

Artificial Sphincter	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups
*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment

SUI Guideline Update Panel

Efficacy - Cure / Dry
ANY Prolapse***Suspensions**

All Open Retropubic
Burch
Laparoscopic

SUBJECTIVE Eval
24 - 47 months

G/P	Median	CI (2.5 - 97.5)%
7/346	83%	(75 - 90)%
6/306	83%	(73 - 91)%
2/186	86%	(59 - 98)%

OBJECTIVE Eval
24 - 47 months

G/P	Median	CI (2.5 - 97.5)%
3/98	78%	(55 - 93)%
2/58	87%	(59 - 99)%
2/201	91%	(85 - 96)%

ANY Eval
24 - 47 months

G/P	Median	CI (2.5 - 97.5)%
9/403	83%	(75 - 90)%
7/333	85%	(75 - 93)%
7/359	83%	(73 - 91)%

Slings

Autologous fascia without bone anchors
Autologous vaginal wall slings w/out bone anchors
Autologous vaginal wall slings with bone anchors - Suprapubic
Cadaveric with bone anchors - Transvaginal
Cadaveric without bone anchors
Homologous tissue (dermis) without bone anchors
Synthetic at bladder neck with bone anchors - Suprapubic
Synthetic at bladder neck with bone anchors - Transvaginal
Synthetic at bladder neck without bone anchors
Synthetic at midurethra
Other Sling

G/P	Median	CI (2.5 - 97.5)%
1/80	85%	(76 - 92)%
2/60	89%	(64 - 99)%
1/39	39%	(24 - 54)%
1/62	61%	(49 - 73)%
6/543	83%	(74 - 91)%

G/P	Median	CI (2.5 - 97.5)%
1/80	85%	(76 - 92)%
2/60	89%	(64 - 99)%
1/9	87%	(59 - 99)%
2/92	64%	(21 - 95)%
1/19	89%	(70 - 98)%
1/32	81%	(65 - 92)%
3/184	75%	(56 - 90)%
11/881	87%	(81 - 91)%

Injectables

Other non-degradable synthetics

G/P	Median	CI (2.5 - 97.5)%

G/P	Median	CI (2.5 - 97.5)%

Artificial Sphincter

G/P	Median	CI (2.5 - 97.5)%
1/206	81%	(75 - 86)%

G/P	Median	CI (2.5 - 97.5)%
1/206	81%	(75 - 86)%

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel

Efficacy - Cure / Dry
ANY Prolapse*

Suspensions
All Open Retropubic
Burch
Laparoscopic

SUBJECTIVE Eval
48 months and greater

G/P	Median	CI (2.5 - 97.5)%
7/541	75%	(61 - 87)%
6/423	71%	(55 - 85)%

OBJECTIVE Eval
48 months and greater

G/P	Median	CI (2.5 - 97.5)%
1/56	80%	(69 - 89)%
1/56	80%	(69 - 89)%

ANY Eval

48 months and greater

G/P	Median	CI (2.5 - 97.5)%
13/1072	67%	(56 - 76)%
12/954	65%	(53 - 74)%
1/34	88%	(74 - 96)%

Slings

Autologous fascia without bone anchors
Autologous vaginal wall slings w/without bone anchors
Autologous vaginal wall slings with bone anchors - Suprapubic
Cadaveric with bone anchors - Transvaginal
Cadaveric without bone anchors
Homologous tissue (dermis) without bone anchors
Synthetic at bladder neck with bone anchors - Suprapubic
Synthetic at bladder neck with bone anchors - Transvaginal
Synthetic at bladder neck without bone anchors
Synthetic at midurethra
Other Sling

SUBJECTIVE Eval
48 months and greater

G/P	Median	CI (2.5 - 97.5)%
1/13	31%	(11 - 58)%
1/90	82%	(73 - 89)%

OBJECTIVE Eval
48 months and greater

G/P	Median	CI (2.5 - 97.5)%
1/82	95%	(89 - 98)%
1/13	31%	(11 - 58)%
1/49	85%	(74 - 93)%
3/182	73%	(62 - 82)%
2/101	76%	(64 - 85)%

Injectables

Other non-degradable synthetics

G/P	Median	CI (2.5 - 97.5)%
1/16	32%	(13 - 56)%

G/P	Median	CI (2.5 - 97.5)%
1/16	32%	(13 - 56)%

G/P	Median	CI (2.5 - 97.5)%
1/16	32%	(13 - 56)%

Artificial Sphincter

G/P	Median	CI (2.5 - 97.5)%

G/P	Median	CI (2.5 - 97.5)%

G/P	Median	CI (2.5 - 97.5)%

Note: **G/P**: G = Number of Groups/Treatment arms extracted / **P** = Number of Patients in those groups

*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A8 -Efficacy - Cure.Dry Improved Rates. Any Prolapse SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved ANY Prolapse*

SUBJECTIVE Eval
12 - 23 months

OBJECTIVE Eval
12 - 23 months

ANY Eval
12 - 23 months

Suspensions	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
All Open Retropubic	8/638	89%	(86 - 92)%	4/189	92%	(86 - 97)%	12/849	90%	(86 - 97)%
Burch	8/638	89%	(86 - 92)%	4/189	92%	(86 - 97)%	12/849	90%	(87 - 92)%
Laparoscopic	3/150	88%	(79 - 94)%	6/224	85%	(78 - 91)%	14/642	88%	(85 - 91)%

Slings	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
Autologous fascia without bone anchors	1/36	89%	(76 - 96)%	2/42	97%	(87 - 100)%	3/78	92%	(82 - 97)%
Autologous vaginal wall slings w/without bone anchors							1/20	99%	(88 - 100)%
Autologous vaginal wall slings with bone anchors - Suprapubic							1/19	99%	(88 - 100)%
Cadaveric with bone anchors - Transvaginal	1/234	82%	(77 - 86)%				1/234	82%	(77 - 86)%
Cadaveric without bone anchors	3/133	81%	(69 - 90)%				3/133	81%	(69 - 90)%
Homologous tissue (dermis) without bone anchors									
Synthetic at bladder neck with bone anchors - Suprapubic									
Synthetic at bladder neck with bone anchors - Transvaginal									
Synthetic at bladder neck without bone anchors	9/688	92%	(88 - 95)%	8/460	89%	(81 - 94)%	1/20	99%	(88 - 100)%
Synthetic at midurethra							15/1121	93%	(89 - 95)%
Other Sling							1/126	94%	(89 - 97)%

Injectables	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
Other non-degradable synthetics									

Artificial Sphincter	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups
 *By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A8 -Efficacy - Cure.Dry Improved Rates. Any Prolapse SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved ANY Prolapse*

SUBJECTIVE Eval
24 - 47 months

OBJECTIVE Eval
24 - 47 months

ANY Eval
24 - 47 months

SUSPENSIONS		SUBJECTIVE Eval		OBJECTIVE Eval		ANY Eval	
		G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
All Open Retropubic		7/346	93%	4/174	83%	10/459	91%
Burch		6/306	92%	3/134	89%	8/389	92%
Laparoscopic		3/199	89%	2/201	95%	8/372	89%
SLINGS		G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Autologous fascia without bone anchors		1/80	95%			1/80	95%
Autologous vaginal wall slings w/without bone anchors		2/60	93%			2/60	93%
Autologous vaginal wall slings with bone anchors - Suprapubic						1/9	87%
Cadaveric with bone anchors - Transvaginal							
Cadaveric without bone anchors		1/39	39%			2/92	64%
Homologous tissue (dermis) without bone anchors				1/19	94%	1/19	94%
Synthetic at bladder neck with bone anchors - Suprapubic							
Synthetic at bladder neck with bone anchors - Transvaginal		1/98	76%			1/32	87%
Synthetic at bladder neck without bone anchors		6/543	91%	1/62	61%	3/184	75%
Synthetic at midurethra				4/446	95%	10/769	92%
Other Sling							
INJECTABLES		G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Other non-degradable synthetics							
ARTIFICIAL SPHINCTER		G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
		1/206	88%			1/206	88%

Note: **G/P**: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups
*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A8 -Efficacy - Cure.Dry Improved Rates. Any Prolapse SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved ANY Prolapse*

	SUBJECTIVE Eval		OBJECTIVE Eval		ANY Eval	
	48 months and greater		48 months and greater		48 months and greater	
Suspensions	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
All Open Retropubic	8/557	80% (70 - 87)%	3/110	80% (70 - 88)%	15/1118	78% (71 - 83)%
Burch	7/439	77% (66 - 86)%	3/100	80% (70 - 88)%	14/1000	76% (69 - 82)%
Laparoscopic					1/34	88% (74 - 96)%
Slings	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Autologous fascia without bone anchors	1/198	70% (63 - 76)%			1/198	70% (63 - 76)%
Autologous vaginal wall slings w/out bone anchors					1/82	95% (89 - 98)%
Autologous vaginal wall slings with bone anchors - Suprapubic						
Cadaveric with bone anchors - Transvaginal						
Cadaveric without bone anchors	1/13	61% (35 - 84)%			1/13	61% (35 - 84)%
Homologous tissue (dermis) without bone anchors						
Synthetic at bladder neck with bone anchors - Suprapubic					1/49	90% (79 - 96)%
Synthetic at bladder neck with bone anchors - Transvaginal						
Synthetic at bladder neck without bone anchors	1/90	82% (73 - 89)%			3/182	73% (62 - 82)%
Synthetic at midurethra					2/101	81% (70 - 90)%
Other Sling						
Injectables	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Other non-degradable synthetics					1/16	56% (33 - 78)%
Artificial Sphincter	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%

Note: **G/P**: **G** = Number of Groups/Treatment arms extracted / **P** = Number of Patients in those groups

*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A9 -Retention Rates.Any Prolapse SUI Guideline Update Panel

Retention ANY Prolapse*

Suspensions	> 28 days or Intervention		
	G/P	Median	CI (2.5 - 97.5)%
All Open Retropubic	13/851	1%	(1 - 3)%
Burch	10/710	1%	(1 - 3)%
Laparoscopic	11/482	2%	(1 - 4)%

Slings	> 28 days or Intervention		
	G/P	Median	CI (2.5 - 97.5)%
Autologous fascia without bone anchors	3/301	5%	(2 - 11)%
Autologous vaginal wall slings w/out bone anchors	3/142	5%	(1 - 17)%
Autologous vaginal wall slings with bone anchors - Suprapubic	1/25	1%	(0 - 9)%
Cadaveric without bone anchors	1/26	1%	(0 - 10)%
Synthetic at bladder neck with bone anchors - Suprapubic	1/49	4%	(1 - 12)%
Synthetic at bladder neck with bone anchors - Transvaginal	2/99	1%	(0 - 6)%
Synthetic at bladder neck without bone anchors	7/422	10%	(5 - 18)%
Synthetic at midurethra	11/1107	3%	(2 - 5)%

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A10 -Urgency rates,Any Prolapse SUI Guideline Update Panel

Urgency ANY Prolapse*

Urge Incontinence									
Suspensions	New Onset			Pre-Existing			Unspecified		
	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
All Open Retropubic	10/457	14%	(8 - 21)%	2/143	22%	(4 - 56)%	2/256	13%	(7 - 22)%
Burch	9/417	14%	(8 - 22)%	1/25	48%	(30 - 67)%	2/256	13%	(7 - 22)%
Laparoscopic	5/344	11%	(6 - 17)%				1/32	4%	(0 - 14)%
Slings									
Autologous fascia without bone anchors	2/97	10%	(4 - 19)%						
Autologous vaginal wall slings w/without bone anchors	3/65	13%	(2 - 36)%	2/15	47%	(21 - 75)%			
Autologous vaginal wall slings with bone anchors - Suprapubic	1/9	13%	(1 - 41)%						
Cadaveric with bone anchors - Transvaginal	1/238	6%	(3 - 9)%						
Cadaveric without bone anchors									
Homologous tissue (dermis) without bone anchors	1/5	22%	(2 - 63)%						
Synthetic at bladder neck with bone anchors - Suprapubic									
Synthetic at bladder neck with bone anchors - Transvaginal									
Synthetic at bladder neck without bone anchors	4/150	15%	(5 - 31)%	3/119	29%	(16 - 46)%			
Synthetic at midurethra	11/805	11%	(7 - 16)%	5/107	52%	(38 - 66)%	2/174	9%	(1 - 38)%
Other Sling									
Injectables									
Artificial Sphincter									

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups
*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

**Urgency
ANY Prolapse***

Suspensions	All Open Retropubic Burch Laparoscopic
1	1
2	2
3	3
4	4
5	5
6	6
7	7
8	8
9	9
10	10
11	11
12	12
13	13
14	14
15	15
16	16
17	17
18	18
19	19
20	20
21	21
22	22
23	23
24	24
25	25
26	26
27	27
28	28
29	29
30	30
31	31
32	32
33	33
34	34
35	35
36	36
37	37
38	38
39	39
40	40
41	41
42	42
43	43
44	44
45	45
46	46
47	47
48	48
49	49
50	50
51	51
52	52
53	53
54	54
55	55
56	56
57	57
58	58
59	59
60	60
61	61
62	62
63	63
64	64
65	65
66	66
67	67
68	68
69	69
70	70
71	71
72	72
73	73
74	74
75	75
76	76
77	77
78	78
79	79
80	80
81	81
82	82
83	83
84	84
85	85
86	86
87	87
88	88
89	89
90	90
91	91
92	92
93	93
94	94
95	95
96	96
97	97
98	98
99	99
100	100

Slings
Autologous fascia without bone anchors
Autologous vaginal wall slings w/out bone anchors
Autologous vaginal wall slings with bone anchors - Suprapubic
Cadaveric with bone anchors - Transvaginal
Cadaveric without bone anchors
Homologous tissue (dermis) without bone anchors
Synthetic at bladder neck with bone anchors - Suprapubic
Synthetic at bladder neck with bone anchors - Transvaginal
Synthetic at bladder neck without bone anchors
Synthetic at midurethra
Other Sling

Injectables

Artificial Sphincter

Note: **G/P**: **G** = Number of **Groups**/Treatment arms extracted / **P** = Number of **Patients** in those groups

*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A10 -Urgency rates,Any Prolapse SUI Guideline Update Panel

Urgency ANY Prolapse*

Unspecified Urgency									
New Onset					Pre-Existing				
G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	Unspecified
2/85	16%	(8 - 27)%							
2/85	16%	(8 - 27)%							
2/73	12%	(5 - 23)%	1/51	6%	(2 - 15)%	1/30	24%	(11 - 40)%	

Suspensions	All Open Retropubic Burch Laparoscopic
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Slings	Autologous fascia without bone anchors Autologous vaginal wall slings w/without bone anchors Autologous vaginal wall slings with bone anchors - Suprapubic Cadaveric with bone anchors - Transvaginal Cadaveric without bone anchors Homologous tissue (dermis) without bone anchors Synthetic at bladder neck with bone anchors - Suprapubic Synthetic at bladder neck with bone anchors - Transvaginal Synthetic at bladder neck without bone anchors Synthetic at midurethra Other Sling
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Injectables	
Artificial Sphincter	

1/45	1%	(0 - 5)%				1/45	1%	(0 - 5)%	
						1/36	17%	(7 - 31)%	
2/69	5%	(0 - 21)%							
1/16	1%	(0 - 14)%	1/59	26%	(16 - 38)%	2/214	7%	(4 - 12)%	

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups
*By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel

Complications

ANY Prolapse**

Death

Transfusion

General Medical Complications

- Cardiovascular
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Operative CX - Other
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Abdominal
- Vaginal

Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

Conversion

Other Complications

Suspensions								
All Retropubic Suspensions			Burch Suspension			Laparoscopic Suspension		
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
7/415	6%	(2 - 14)%	6/375	7%	(2 - 16)%	5/183	2%	(1 - 6)%
3/342	2%	(1 - 4)%	3/342	2%	(1 - 4)%	3/185	3%	(1 - 6)%
7/614	11%	(5 - 20)%	5/513	14%	(6 - 26)%	3/296	2%	(1 - 5)%
2/280	12%	(6 - 19)%	2/280	12%	(6 - 19)%			
1/51	3%	(1 - 7)%	1/51	3%	(1 - 7)%	2/164	3%	(1 - 9)%
1/33	4%	(0 - 13)%				2/151	3%	(1 - 7)%
1/82	4%	(1 - 9)%	1/82	4%	(1 - 9)%	2/149	3%	(1 - 8)%
10/779	17%	(11 - 25)%	10/779	17%	(11 - 25)%	11/545	7%	(5 - 11)%
8/503	3%	(2 - 6)%	8/503	3%	(2 - 6)%	16/901	6%	(4 - 8)%
2/177	5%	(1 - 13)%	2/177	5%	(1 - 13)%	2/98	2%	(0 - 8)%
9/600	5%	(3 - 7)%	8/560	5%	(3 - 7)%	7/366	3%	(2 - 6)%
2/150	2%	(0 - 6)%	1/82	1%	(0 - 6)%	3/182	3%	(1 - 8)%
2/147	2%	(0 - 5)%	2/147	2%	(0 - 5)%	4/201	6%	(2 - 11)%
1/127	1%	(0 - 4)%	1/127	1%	(0 - 4)%	1/36	1%	(0 - 7)%
2/2	71%	(23 - 98)%		*				
	*			*		3/109	4%	(1 - 10)%
	*			*				
						1/113	1%	(0 - 4)%
5/408	5%	(3 - 9)%	5/408	5%	(3 - 9)%	4/206	4%	(1 - 8)%
3/233	5%	(1 - 12)%	1/132	1%	(0 - 3)%	4/155	7%	(2 - 18)%
						1/48	0%	(0 - 5)%
2/76	9%	(2 - 24)%	2/76	9%	(2 - 24)%	7/353	3%	(2 - 6)%
5/262	7%	(4 - 12)%	5/262	7%	(4 - 12)%	1/34	12%	(4 - 26)%
3/314	16%	(5 - 33)%	3/314	16%	(5 - 33)%	3/104	8%	(3 - 15)%
						3/219	11%	(5 - 20)%
3/183	8%	(4 - 14)%	3/183	8%	(4 - 14)%	1/36	6%	(1 - 17)%

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel

Complications

ANY Prolapse**

Death

Transfusion

General Medical Complications

- Cardiovascular
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

Slings										
Autologous fascia				Autologous Vaginal Wall Slings						
without Bone Anchors				with/without Bone anchors			w Bone Anchors - Suprapubic			
G/P	Med	CI (2.5 - 97.5)%		G/P	Med	CI (2.5 - 97.5)%		G/P	Med	CI (2.5 - 97.5)%
1/198	4%	(2 - 7)%		2/35	9%	(2 - 24)%				

		1/15	8%	(1 - 27)%		
1/80	4%	(1 - 10)%	2/32	22%	(8 - 42)%	
1/80	10%	(5 - 18)%				
1/80	8%	(3 - 15)%	1/20	1%	(0 - 12)%	

Operative Complications

Bladder Injury
Bleeding
Bleeding - Acute
Bleeding - Hematoma
Bowel Injury
Erosion Extrusion
Erosion Extrusion - Unknown
Erosion Extrusion - Urethral-Bladder
Erosion Extrusion - Vaginal
Nerve Injury
Operative CX - Other
Osteomyelitis
Ureteral Injury
Urethral Injury
Urinary Tract Injury NS
Vaginal Operative CX
Wound
Abdominal
Vaginal

2/278	8%	(1 - 26)%	1/82	3%	(1 - 8)%		
1/80	8%	(3 - 15)%	1/20	6%	(1 - 21)%		
1/80	1%	(0 - 6)%					
	*		1/20	1%	(0 - 12)%		
			1/82	1%	(0 - 6)%		
							*
			1/20	1%	(0 - 12)%		
2/278	4%	(2 - 8)%					
			1/82	3%	(1 - 8)%		*
			2/65	3%	(0 - 11)%		

Subjective Complications

	Pain
Sexual Dysfunction	
Voiding Dysfunction	

1/80	3%	(1 - 8)%	1/45	3%	(0 - 10)%		

Conversion

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Other Complications

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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel
Complications
ANY Prolapse**

Death

Transfusion

General Medical Complications

Cardiovascular
 Febrile
 Infection
 Infection/Local Extension
 Neurologic
 Pulmonary
 Systemic - Abscess
 UTI

Operative Complications

Bladder Injury
 Bleeding
 Bleeding - Acute
 Bleeding - Hematoma
 Bowel Injury
 Erosion Extrusion
 Erosion Extrusion - Unknown
 Erosion Extrusion - Urethral-Bladder
 Erosion Extrusion - Vaginal
 Nerve Injury
 Operative CX - Other
 Osteomyelitis
 Ureteral Injury
 Urethral Injury
 Urinary Tract Injury NS
 Vaginal Operative CX
 Wound
 Abdominal
 Vaginal

Subjective Complications

Pain
 Sexual Dysfunction
 Voiding Dysfunction

Conversion

Other Complications

Slings

Synthetic at Bladder Neck

with Bone Anchors			w Bone Anchors - Suprapubic			without Bone Anchors		
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
						2/92	53%	(40 - 66)%

						1/47	2%	(0 - 10)%
			1/49	0%	(0 - 5)%	1/20	25%	(10 - 46)%
						3/112	9%	(4 - 17)%

						1/24	1%	(0 - 10)%
						3/112	11%	(3 - 24)%
						2/143	12%	(2 - 36)%
			1/49	2%	(0 - 9)%	1/20	1%	(0 - 12)%
			1/49	0%	(0 - 5)%	4/223	9%	(5 - 19)%
	*							
						1/98	1%	(0 - 12)%
						1/98	20%	(14 - 30)%
						1/98	40%	(31 - 50)%
						1/98	26%	(18 - 35)%
						1/20	1%	(0 - 12)%

		1/49	4%	(1 - 12)%	1/62	2%	(0 - 7)%
		1/49	4%	(1 - 12)%			
		1/49	0%	(0 - 5)%	2/122	16%	(3 - 38)%

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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

**By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel
Complications
ANY Prolapse**

Death

Transfusion

General Medical Complications

- Cardiovascular
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Operative CX - Other
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Abdominal
- Vaginal

Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

Conversion

Other Complications

Slings									
Synthetic at Midurethra			Xenograft			Other Sling			
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	
9/3189	1%	(0 - 1)%				1/126	0%	(0 - 2)%	
2/2113	0%	(0 - 1)%							
3/468	8%	(4 - 14)%							
1/1455	1%	(0 - 1)%	1/18	17%	(5 - 38)%				
	*								
1/75	2%	(0 - 6)%							
2/111	3%	(1 - 9)%	1/10	60%	(30 - 85)%				
16/3016	7%	(5 - 9)%				1/126	1%	(0 - 4)%	
29/4248	6%	(5 - 8)%				1/126	3%	(1 - 6)%	
6/1921	2%	(1 - 3)%				1/126	0%	(0 - 2)%	
15/3770	3%	(2 - 4)%							
	*								
6/632	4%	(2 - 7)%							
5/308	3%	(1 - 8)%							
6/2185	2%	(1 - 5)%							
3/1891	1%	(0 - 2)%							
5/1801	2%	(1 - 3)%				1/126	0%	(0 - 2)%	
3/393	1%	(0 - 3)%	1/18	17%	(5 - 38)%	1/126	5%	(2 - 10)%	
2/301	2%	(0 - 6)%							
3/1612	1%	(0 - 2)%							
1/45	1%	(0 - 5)%							

4/1985	3%	(1 - 7)%					
9/2407	16%	(6 - 33)%					

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1/193	1%	(0 - 2)%					
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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group
 * Only case reports of this complication exist, and data are insufficient to estimate the frequency.
 **By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

SUI Guideline Update Panel
Complications
ANY Prolapse**

Death

Transfusion

General Medical Complications

- Cardiovascular
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

Injectables						Artificial Sphincter					
Collagen						Artificial Sphincter					
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
1/105	2%	(0 - 6)%									

Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Operative CX - Other
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Abdominal
- Vaginal

		2/206	15%	(10 - 22)%
		1/179	4%	(2 - 8)%
		1/206	7%	(4 - 11)%
		1/206	3%	(1 - 6)%
		2/206	2%	(0 - 9)%
		2/206	13%	(6 - 22)%
		1/179	7%	(4 - 12)%

Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

Conversion

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Other Complications

		1/206	3%	(2 - 7)%
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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those group
 * Only case reports of this complication exist, and data are insufficient to estimate the frequency.
 **By any evaluation method, including subjective and objective; includes groups/arms in which ANY patient had a concurrent prolapse treatment.

Appendix A12 -Efficacy - Cure.Dry Rates. No Prolapse SUI Guideline Update Panel

Efficacy - Cure / Dry NO Prolapse

	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Suspensions						
All Open Retropubic	12/867	80% (71 - 87)%	6/369	82% (74 - 89)%	15/1085	82% (74 - 87)%
Burch	11/862	79% (69 - 87)%	5/354	81% (72 - 89)%	14/1070	81% (73 - 87)%
Laparoscopic	4/189	66% (40 - 87)%	5/234	74% (64 - 83)%	9/368	69% (52 - 84)%
Slings						
Autologous fascia without bone anchors	2/283	82% (59 - 95)%			4/342	90% (76 - 98)%
Autologous vaginal wall slings w/out bone anchors	1/39	79% (65 - 90)%			1/39	79% (65 - 90)%
Autologous vaginal wall slings with bone anchors						
Cadaveric without bone anchors	1/104	74% (65 - 82)%			1/104	74% (65 - 82)%
Synthetic at bladder neck with bone anchors	1/24	91% (76 - 98)%			2/34	88% (71 - 97)%
Synthetic at bladder neck without bone anchors						
Synthetic at midurethra	10/917	85% (79 - 90)%	6/756	88% (85 - 91)%	14/1215	84% (78 - 89)%
Injectables						
Collagen	4/207	50% (39 - 61)%	4/128	55% (44 - 64)%	7/340	48% (41 - 55)%
Artificial Sphincter						

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

Appendix A12 -Efficacy - Cure.Dry Rates. No Prolapse SUI Guideline Update Panel

Efficacy - Cure / Dry NO Prolapse

	SUBJECTIVE Eval 24 - 47 months		OBJECTIVE Eval 24 - 47 months		ANY Eval 24 - 47 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Suspensions All Open Retropubic Burch Laparoscopic	6/478	74%	2/137	81%	13/803	76%
	5/450	74%	2/137	81%	12/775	76%
	4/172	74%	2/53	56%	4/172	74%
Slings Autologous fascia without bone anchors Autologous vaginal wall slings w/out bone anchors Autologous vaginal wall slings with bone anchors Cadaveric without bone anchors Synthetic at bladder neck with bone anchors Synthetic at bladder neck without bone anchors Synthetic at midurethra	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
	3/125	82%			6/232	81%
	1/58	79%			1/58	79%
	1/63	71%			2/71	80%
	3/101	69%	4/62	60%	9/349	73%
	2/188	67%	3/258	84%	7/483	81%
Injectables Collagen	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
	1/26	39%	3/95	42%	4/210	32%
Artificial Sphincter	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
					3/78	83%

Note: **G/P:** G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

Appendix A12 -Efficacy - Cure.Dry Rates. No Prolapse

SUI Guideline Update Panel

Efficacy - Cure / Dry NO Prolapse

Suspensions	SUBJECTIVE Eval		OBJECTIVE Eval		ANY Eval	
	48 months and greater		48 months and greater		48 months and greater	
All Open Retropubic	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Burch	10/691	65% (55 - 74)%	3/157	69% (55 - 82)%	17/1259	73% (64 - 77)%
Laparoscopic	7/598	68% (55 - 79)%	3/157	69% (55 - 82)%	13/1065	73% (65 - 80)%
Slings	SUBJECTIVE Eval		OBJECTIVE Eval		ANY Eval	
	48 months and greater		48 months and greater		48 months and greater	
Autologous fascia without bone anchors	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Autologous vaginal wall slings w/out bone anchors	2/284	71% (38 - 93)%			4/368	82% (67 - 93)%
Autologous vaginal wall slings with bone anchors					1/29	96% (85 - 100)%
Cadaveric without bone anchors						
Synthetic at bladder neck with bone anchors						
Synthetic at bladder neck without bone anchors					1/27	92% (78 - 98)%
Synthetic at midurethra			1/80	85% (76 - 92)%	3/199	84% (77 - 89)%
Injectables	SUBJECTIVE Eval		OBJECTIVE Eval		ANY Eval	
	48 months and greater		48 months and greater		48 months and greater	
Collagen	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
					1/40	30% (18 - 45)%
Artificial Sphincter	SUBJECTIVE Eval		OBJECTIVE Eval		ANY Eval	
	48 months and greater		48 months and greater		48 months and greater	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

Appendix A13 -Efficacy - Cure.Dry Improved Rates. No Prolapse SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved NO Prolapse

Suspensions	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
All Open Retropubic	13/950	86% (81 - 90)%	6/431	84% (78 - 89)%	16/1168	86% (82 - 90)%
Burch	12/935	86% (81 - 89)%	6/431	84% (78 - 89)%	15/1143	86% (81 - 89)%
Laparoscopic	6/242	89% (83 - 94)%	7/287	77% (66 - 86)%	10/370	87% (79 - 93)%
Slings	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
	Autologous fascia without bone anchors					
	2/283	92% (88 - 96)%			4/342	93% (89 - 95)%
	Autologous vaginal wall slings w/out bone anchors					
	1/39	79% (65 - 90)%			1/39	79% (65 - 90)%
Injectables	Autologous vaginal wall slings with bone anchors					
	Cadaveric without bone anchors					
	1/104	93% (87 - 97)%			1/104	93% (87 - 97)%
	Synthetic at bladder neck with bone anchors					
Artificial Sphincter	1/24	91% (76 - 98)%			2/34	88% (71 - 97)%
	Synthetic at bladder neck without bone anchors					
	10/917	90% (86 - 94)%	6/674	89% (86 - 92)%	13/1166	88% (82 - 92)%
Injectables	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
Collagen	4/207	76% (69 - 82)%	4/128	57% (46 - 68)%	7/340	69% (62 - 75)%
Artificial Sphincter	SUBJECTIVE Eval 12 - 23 months		OBJECTIVE Eval 12 - 23 months		ANY Eval 12 - 23 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

Appendix A13 -Efficacy - Cure.Dry Improved Rates. No Prolapse SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved NO Prolapse

SUSPENSIONS	SUBJECTIVE Eval 24 - 47 months		OBJECTIVE Eval 24 - 47 months		ANY Eval 24 - 47 months	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
All Open Retropubic Burch Laparoscopic	6/478	82% (73 - 90)%	2/137	81% (70 - 89)%	13/903	83% (77 - 88)%
	5/450	83% (73 - 91)%	2/137	81% (70 - 89)%	12/775	84% (77 - 89)%
	4/172	74% (61 - 85)%	2/53	56% (31 - 80)%	4/172	74% (61 - 85)%
SLINGS	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
	3/125	92% (81 - 98)%			6/232	92% (84 - 96)%
	1/58	79% (68 - 88)%			1/58	79% (68 - 88)%
	1/63	78% (66 - 87)%			2/72	80% (60 - 93)%
Autologous fascia without bone anchors Autologous vaginal wall slings w/out bone anchors Autologous vaginal wall slings with bone anchors Cadaveric without bone anchors Synthetic at bladder neck with bone anchors Synthetic at bladder neck without bone anchors Synthetic at midurethra	3/101	87% (72 - 96)%	4/62	60% (43 - 75)%	9/349	80% (71 - 88)%
	2/188	71% (24 - 97)%	3/258	89% (78 - 96)%	9/587	92% (84 - 97)%
INJECTABLES	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
	1/26	69% (50 - 84)%	3/95	45% (29 - 61)%	4/210	55% (41 - 69)%
Collagen						
ARTIFICIAL SPHINCTER	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
					3/78	91% (81 - 97)%

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

Appendix A13 -Efficacy - Cure.Dry Improved Rates. No Prolapse SUI Guideline Update Panel

Efficacy - Cure / Dry / Improved NO Prolapse

Suspensions	SUBJECTIVE Eval 48 months and greater		OBJECTIVE Eval 48 months and greater		ANY Eval 48 months and greater	
	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
All Open Retropubic Burch Laparoscopic	10/691	79% (69 - 86)%	3/157	69% (55 - 82)%	17/1259	79% (73 - 85)%
	7/598	84% (76 - 90)	3/157	69% (55 - 82)%	13/1065	83% (76 - 88)%
Slings	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
	2/284	81% (63 - 93)%			4/368	86% (78 - 92)%
					1/29	96% (85 - 100)%
Injectables	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%
					1/40	70% (55 - 82)%
Artificial Sphincter	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%	G/P	Median CI (2.5 - 97.5)%

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

Retention NO Prolapse

		> 28 days or Intervention		
Suspensions		G/P	Median	CI (2.5 - 97.5)%
All Open Retropubic		8/619	4%	(1 - 8)%
Burch		5/347	3%	(1 - 7)%
Laparoscopic		5/188	4%	(1 - 8)%

Slings		G/P	Median	CI (2.5 - 97.5)%
Autologous fascia without bone anchors		8/480	8%	(4 - 15)%
Autologous vaginal wall slings w/without bone anchors		2/68	2%	(0 - 8)%
Synthetic at bladder neck without bone anchors		4/360	9%	(5 - 15)%
Synthetic at midurethra		17/2119	3%	(2 - 4)%

Injectables		G/P	Median	CI (2.5 - 97.5)%
Collagen		2/104	1%	(0 - 5)%

Note: **G/P:** **G** = Number of Groups/Treatment arms extracted / **P** = Number of Patients in those groups

Appendix A15 -Urgency rates,No Prolapse SUI Guideline Update Panel

Urgency NO Prolapse

Urgency Incontinence									
Suspensions	New Onset			Pre-Existing			Unspecified		
	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
All Open Retropubic	10/713	8%	(5 - 12)%	5/186	14%	(6 - 25)%	4/305	41%	(30 - 54)%
Burch	9/695	8%	(5 - 11)%	3/108	17%	(4 - 40)%	4/305	41%	(30 - 54)%
Laparoscopic	2/112	5%	(1 - 14)%				2/100	6%	(1 - 14)%
Slings	New Onset			Pre-Existing			Unspecified		
	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
Autologous fascia without bone anchors	4/329	9%	(6 - 13)%	4/358	33%	(28 - 40)%			
Autologous vaginal wall slings w/without bone anchors				1/13	9%	(1 - 31)%			
Cadaveric without bone anchors	1/25	28%	(13 - 47)%	1/38	21%	(10 - 36)%			
Synthetic at bladder neck with bone anchors				1/6	96%	(67 - 100)%			
Synthetic at bladder neck without bone anchors	4/132	12%	(6 - 20)%	1/24	17%	(6 - 35)%			
Synthetic at midurethra	7/323	6%	(3 - 10)%	1/25	44%	(26 - 63)%	2/532	22%	(3 - 58)%
Injectables	New Onset			Pre-Existing			Unspecified		
	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
Collagen	1/337	13%	(10 - 17)%				1/50	8%	(3 - 18)%

Appendix A15 -Urgency rates,No Prolapse SUI Guideline Update Panel

Urgency NO Prolapse

Urgency Symptoms									
	New Onset			Pre-Existing			Unspecified		
	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
Suspensions	5/476	15%	(7 - 27)%	1/90	0%	(0 - 3)%	1/102	0%	(0 - 2)%
	5/476	15%	(7 - 27)%	1/90	0%	(0 - 3)%	1/102	0%	(0 - 2)%
Slings	5/228	16%	(10 - 23)%	3/63	41%	(28 - 55)%			
	1/8	14%	(1 - 45)%						
	3/108	13%	(6 - 23)%						
Injectables	4/190	14%	(5 - 30)%	4/178	38%	(27 - 50)%	2/532	45%	(11 - 83)%
Collagen									

Appendix A15 -Urgency rates,No Prolapse SUI Guideline Update Panel

Urgency NO Prolapse

Unspecified Urgency									
	New Onset			Pre-Existing			Unspecified		
	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%	G/P	Median	CI (2.5 - 97.5)%
Suspensions All Open Retropubic Burch Laparoscopic	2/95	28%	(18 - 40)%	2/116	23%	(11 - 39)%	1/36	9%	(2 - 21)%
	2/95	28%	(18 - 40)%	2/116	23%	(11 - 39)%	1/36	9%	(2 - 21)%
							2/55	9%	(2 - 23)%
Slings Autologous fascia without bone anchors Autologous vaginal wall slings w/without bone anchors Cadaveric without bone anchors Synthetic at bladder neck with bone anchors Synthetic at bladder neck without bone anchors Synthetic at midurethra	1/10	11%	(1 - 38)%	1/15	40%	(19 - 65)%			
	1/53	32%	(21 - 45)%						
Injectables Collagen	3/86	17%	(6 - 35)%				1/28	36%	(20 - 54)%

SUI Guideline Update Panel
Complications
NO Prolapse

Death

Transfusion

General Medical Complications

- Cardiovascular
- Dermatologic
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Wound - Abdominal
- Wound - Vaginal

Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

Conversion

Other Complications

Suspensions								
All Retropubic Suspensions			Burch Suspension			Laparoscopic Suspension		
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
2/170	3%	(0 - 14)%	2/170	3%	(0 - 14)%			
6/321	6%	(2 - 12)%	4/169	9%	(3 - 19)%	1/24	5%	(0 - 18)%
6/592	2%	(1 - 4)%	3/294	3%	(1 - 8)%			
7/426	8%	(5 - 12)%	3/113	11%	(5 - 20)%	1/60	0%	(0 - 4)%
1/98	2%	(0 - 6)%	1/98	2%	(0 - 6)%	1/31	4%	(0 - 14)%
	*			*				
1/113	1%	(0 - 4)%	1/113	1%	(0 - 4)%			
1/15	8%	(1 - 27)%				1/51	2%	(0 - 9)%
1/62	7%	(2 - 15)%	1/62	7%	(2 - 15)%			
17/1442	13%	(9 - 19)%	10/978	15%	(8 - 24)%	1/51	2%	(0 - 9)%
10/887	4%	(2 - 7)%	7/589	6%	(2 - 12)%	5/165	5%	(2 - 10)%
3/433	4%	(1 - 9)%	2/334	2%	(0 - 6)%			
6/484	3%	(2 - 6)%	5/469	3%	(1 - 5)%	1/51	2%	(0 - 9)%
1/31	4%	(0 - 14)%	1/31	4%	(0 - 14)%	1/31	4%	(0 - 14)%
2/102	19%	(1 - 70)%		*				
	*							
5/1739	1%	(1 - 2)%	4/1640	1%	(1 - 2)%	3/57	11%	(1 - 42)%
						2/55	2%	(0 - 10)%
1/60	2%	(0 - 8)%						
13/1229	6%	(4 - 7)%	8/793	6%	(4 - 9)%	1/51	2%	(0 - 9)%
9/761	4%	(3 - 6)%	5/449	4%	(2 - 7)%			

9/980	5%	(3 - 8)%	6/756	6%	(3 - 12)%		*
8/989	4%	(2 - 6)%	5/801	3%	(2 - 4)%		
6/636	9%	(5 - 15)%	5/583	10%	(5 - 18)%	1/60	5% (1 - 13)%

1/17	7%	(1 - 24)%	1/17	7%	(1 - 24)%	3/184	5%	(2 - 9)%
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3/253	5%	(0 - 20)%	2/154	14%	(0 - 66)%	1/51	2%	(0 - 9)%
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Note: **G/P**: **G** = Number of Groups/Treatment arms extracted **P** = Number of Patients in those groups

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

SUI Guideline Update Panel
Complications
NO Prolapse

Death

Transfusion

General Medical Complications

- Cardiovascular
- Dermatologic
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Wound - Abdominal
- Wound - Vaginal

Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

Conversion

Other Complications

Slings								
Autologous fascia			Autologous Vaginal Wall Slings			Cadaveric		
without Bone Anchors			with/without Bone anchors			without Bone Anchors		
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
1/90	0%	(0 - 3)%						
3/194	4%	(1 - 11)%				1/63	0%	(0 - 4)%

2/338	2%	(0 - 5)%						
1/71	0%	(0 - 3)%				1/63	7%	(2 - 14)%
1/30	4%§	(0 - 15)%						
1/91	1%	(0 - 5)%						
						1/104	2%	(0 - 6)%
5/241	16%	(6 - 31)%	2/402	4%	(2 - 7)%	1/63	7%	(2 - 14)%

6/423	4%	(2 - 9)%	1/29	1%	(0 - 8)%			
1/20	6%	(1 - 21)%						
1/247	1%	(0 - 3)%				1/104	1%	(0 - 4)%
1/33	1%	(0 - 7)%					*	
4/370	2%	(0 - 7)%				1/63	0%	(0 - 4)%
			1/373	2%	(1 - 4)%		*	
						1/104	1%	(0 - 4)%
2/111	8%	(3 - 16)%						
1/247	1%	(0 - 3)%	2/402	5%	(3 - 8)%			

3/63	10%	(1 - 35)%						
4/105	8%	(3 - 16)%						
	*					1/8	38%§	(12 - 71)%

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Note: **G/P**: **G** = Number of Groups/Treatment arms extracted **P** = Number of Patients in those groups
 * Only case reports of this complication exist, and data are insufficient to estimate the frequency.
 § Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

SUI Guideline Update Panel

Complications

NO Prolapse

Slings

Synthetic at Bladder Neck

[illegible]

Operative Complications

Bladder Injury	1/11	10%\$	(1 - 35)%				
Bleeding							
Bleeding - Acute							
Bleeding - Hematoma							
Bowel Injury							
Erosion Extrusion - Unknown							
Erosion Extrusion - Urethral-Bladder							*
Erosion Extrusion - Vaginal	1/10	21%\$	(4 - 50)%				*
Nerve Injury							
Osteomyelitis		*		1/108	3%	(1 - 7)%	
Ureteral Injury							
Urethral Injury							
Urinary Tract Injury NS							
Vaginal Operative CX							
Wound							
Wound - Abdominal							
Wound - Vaginal							

Subjective Complications

Pain						
Sexual Dysfunction						
Voiding Dysfunction						

Conversion

Other Complications					

Other Complications

Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

SUI Guideline Update Panel
Complications
NO Prolapse

Death

Transfusion

General Medical Complications

- Cardiovascular
- Dermatologic
- Febrile
- Infection
- Infection/Local Extension
- Neurologic
- Pulmonary
- Systemic - Abscess
- UTI

Operative Complications

- Bladder Injury
- Bleeding
- Bleeding - Acute
- Bleeding - Hematoma
- Bowel Injury
- Erosion Extrusion - Unknown
- Erosion Extrusion - Urethral-Bladder
- Erosion Extrusion - Vaginal
- Nerve Injury
- Osteomyelitis
- Ureteral Injury
- Urethral Injury
- Urinary Tract Injury NS
- Vaginal Operative CX
- Wound
- Wound - Abdominal
- Wound - Vaginal

Subjective Complications

- Pain
- Sexual Dysfunction
- Voiding Dysfunction

Conversion

Other Complications

Slings								
Synthetic at Bladder Neck			Synthetic at Midurethra			Other Sling		
without Bone Anchors								
G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%	G/P	Med	CI (2.5 - 97.5)%
			1/25	1%	(0 - 9)%			
1/200	1%	(0 - 3)%	3/569	2%	(1 - 4)%			
			2/261	1%	(0 - 3)%			
							*	
			2/174	7%	(4 - 13)%			
2/315	3%	(1 - 5)%	1/25	1%	(0 - 9)%			
2/224	10%	(2 - 27)%	9/771	8%	(5 - 13)%			

1/200	1%	(0 - 2)%	23/1925	6%	(4 - 8)%		
			6/705	3%	(1 - 5)%		
			7/1035	3%	(2 - 4)%		
			3/256	1%	(0 - 4)%		
2/501	17%§	(9 - 28)%	6/621	1%	(0 - 3)%		
3/346	3%	(1 - 9)%					
6/591	8%	(4 - 15)%	9/891	7%	(2 - 15)%		*
1/200	1%	(0 - 2)%	1/404	0%	(0 - 1)%		
				*			*
			2/302	2%	(0 - 7)%		
2/385	7%	(3 - 14)%	3/280	2%	(1 - 5)%		
			2/75	2%	(0 - 8)%		
			4/189	4%	(1 - 7)%		

2/264	9%	(2 - 23)%	2/512	1%	(0 - 3)%		
			1/62	0%	(0 - 4)%		
			1/1175	2%	(1 - 3)%		

						*
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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups
 * Only case reports of this complication exist, and data are insufficient to estimate the frequency.
 § Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

SUI Guideline Update Panel

Complications

NO Prolapse

Death					1/25	5%	(0 - 17)%
Transfusion							

General Medical Complications

Cardiovascular							
Dermatologic	3/399	5%	(1 - 17)%				
Febrile							
Infection							
Infection/Local Extension							
Neurologic							
Pulmonary	1/60	2%	(0 - 8)%				
Systemic - Abscess	1/115	1%	(0 - 4)%				
UTI	6/381	10%	(5 - 17)%				

Operative Complications

Bladder Injury						
Bleeding						
Bleeding - Acute	4/251	5%	(3 - 8)%			
Bleeding - Hematoma						
Bowel Injury						
Erosion Extrusion - Unknown					1/18	28% 5 (11 - 51)%
Erosion Extrusion - Urethral-Bladder						
Erosion Extrusion - Vaginal						
Nerve Injury						
Osteomyelitis						
Ureteral Injury						
Urethral Injury		*		*		
Urinary Tract Injury NS						
Vaginal Operative CX						
Wound						
Wound - Abdominal						
Wound - Vaginal						

Subjective Complications

Pain		*				
Sexual Dysfunction						
Voiding Dysfunction						

Conversion

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Other Complications

3/342	27%§	(2 - 76)%			1/18	23%§	(8 - 45)%
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Note: G/P: G = Number of Groups/Treatment arms extracted / P = Number of Patients in those groups

* Only case reports of this complication exist, and data are insufficient to estimate the frequency.

§ Although this estimate is based on some published data, the panel believes the estimates are not consistent with their experience.

**American Urological Association, Inc.
SUI Guidelines Panel**

**Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX**

Artificial Sphincter

Acute Bleeding
Bladder Injury
Bowel Injury
Death
Fistula
Infection - Wound
Other Complications
PE/DVT
Removal of Foreign Body - other
Urethral Erosion
Vascular Injury
Wound - Abdominal Minor
Wound - Vaginal

Autologous fascia with bone anchors - Suprapubic

Infection - UTI
Infection - Wound
None (per Author)

Autologous fascia without bone anchors

Acute Bleeding
Bladder Injury
Bowel Injury
Death
DVT
Dysuria
Hematoma
Infection
Infection - UTI
Infection - Wound
None (per Author)
Other Complications
Pain
PE/DVT
Pulmonary
Removal of Foreign Body - other
Sexual Dysfunction
Stitches
Transfusion

**American Urological Association, Inc.
SUI Guidelines Panel**

**Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX**

Urethral Erosion
Wound - Abdominal
Wound - Abdominal Major
Wound - Abdominal Minor
Wound - Vaginal Minor

Autologous vaginal wall slings w/without bone anchors

Acute Bleeding
Bladder Injury
Death
Dysuria
Fistula
Infection - Local Extension
Infection - UTI
Infection - Wound
MI
None (per Author)
Other Complications
Pain
Sexual Dysfunction
Stitches
Transfusion
Urethral Erosion
Wound - Abdominal
Wound - Abdominal Major
Wound - Abdominal Minor
Wound - Vaginal Major
Wound - Vaginal Minor

Autologous vaginal wall slings with bone anchors - Suprapubic

None (per Author)
Other Complications
Removal of Foreign Body - other
Wound - Abdominal Major

Burch Suspension

Acute Bleeding
Bladder Injury
Bowel Injury
Death

American Urological Association, Inc.
SUI Guidelines Panel

Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX

- DVT
- Dysuria
- Fistula
- Hematoma
- Infection
- Infection - Local Extension
- Infection - Systemic
- Infection - UTI
- Infection - Wound
- None (per Author)
- Other Complications
- Pain
- PE/DVT
- Pulmonary
- Rectal Injury
- Sexual Dysfunction
- Transfusion
- Urethral Erosion
- Vascular Injury
- Wound
- Wound - Abdominal
- Wound - Abdominal Major
- Wound - Abdominal Minor

Cadaveric with bone anchors

- Wound - Vaginal Major

Cadaveric with bone anchors - Transvaginal

- Bladder Injury
- Infection - Systemic
- Infection - UTI
- Other Complications
- Pain
- Sexual Dysfunction
- Wound - Vaginal Minor

Cadaveric without bone anchors

- Bladder Injury
- Hematoma
- Infection - UTI

**American Urological Association, Inc.
SUI Guidelines Panel**

**Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX**

Infection - Wound
Other Complications
Removal of Foreign Body - other
Transfusion
Urethral Erosion
Wound - Abdominal
Wound - Abdominal Major

Collagen

Acute Bleeding
Infection - UTI
Infection - Wound
None (per Author)
Other Complications
Pulmonary

Cooper's ligament sling (all sling materials)

CVA
Death
Hematoma
Other Complications

Homologous tissue (dermis) with bone anchors - Transvaginal

Acute Bleeding
Bladder Injury
Bowel Injury
Infection - Local Extension
Other Complications
Sexual Dysfunction
Wound - Vaginal Minor

Homologous tissue (dermis) without bone anchors

None (per Author)
Other Complications
Wound - Vaginal Major

Laparoscopic Suspension

Acute Bleeding
Bladder Injury

American Urological Association, Inc.
SUI Guidelines Panel

Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX

Bowel Injury
Dysuria
Fistula
Hematoma
Infection
Infection - Local Extension
Infection - Systemic
Infection - UTI
Infection - Wound
None (per Author)
Other Complications
Pain
PE/DVT
Pulmonary
Removal of Foreign Body - other
Sexual Dysfunction
Stitches
Transfusion
Ureteral Injury
Vascular Injury
Wound
Wound - Abdominal
Wound - Abdominal Major
Wound - Abdominal Minor
Wound - Vaginal
Wound - Vaginal Major

MMK

Hematoma
Infection - UTI
Infection - Wound
Other Complications
Pulmonary
Sexual Dysfunction
Stitches
Transfusion
Wound - Abdominal

Open Retropubic Suspensions

Acute Bleeding

**American Urological Association, Inc.
SUI Guidelines Panel**

**Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX**

Bladder Injury
Bowel Injury
Hematoma
Infection - Local Extension
Infection - Systemic
Infection - UTI
Infection - Wound
Other Complications
PE/DVT
Transfusion
Vascular Injury
Wound - Abdominal Major
Wound - Abdominal Minor

Other degradable materials

Death
Hematoma
Infection - UTI
Other Complications
PE/DVT

Other Injectables

Death
Infection - UTI
Other Complications
Removal of Foreign Body - other
Wound - Abdominal Major
Wound - Abdominal Minor

Other non-degradable synthetics

Dysuria
Infection - UTI
Other Complications

Other Sling

Acute Bleeding
Bladder Injury
Infection
Infection - UTI

**American Urological Association, Inc.
SUI Guidelines Panel**

**Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX**

None (per Author)
Other Complications
Transfusion
Wound - Vaginal Major

Other Suspensions

Acute Bleeding
Bladder Injury
Bowel Injury
Dysuria
Hematoma
Infection - Systemic
Infection - UTI
Infection - Wound
None (per Author)
Other Complications
PE/DVT
Pulmonary
Removal of Foreign Body - other
Sexual Dysfunction
Stitches
Transfusion
Wound - Abdominal Minor

Synthetic at bladder neck with bone anchors

Bladder Injury
None (per Author)
Other Complications
Wound - Vaginal

Synthetic at bladder neck with bone anchors - Suprapubic

Bladder Injury
Infection
Other Complications
Removal of Foreign Body - other
Sexual Dysfunction
Urethral Erosion
Wound - Abdominal Minor

**American Urological Association, Inc.
SUI Guidelines Panel**

**Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX**

Synthetic at bladder neck with bone anchors - Transvaginal

Acute Bleeding
Bladder Injury
Hematoma
Infection - UTI
Infection - Wound
Other Complications
Removal of Foreign Body - other
Sexual Dysfunction
Urethral Erosion
Wound - Vaginal Major
Wound - Vaginal Minor

Synthetic at bladder neck without bone anchors

Acute Bleeding
Bladder Injury
Bowel Injury
Hematoma
Infection - Systemic
Infection - UTI
Infection - Wound
MI
None (per Author)
Other Complications
Pulmonary
Removal of Foreign Body - other
Sexual Dysfunction
Stitches
Transfusion
Urethral Erosion
Wound
Wound - Abdominal
Wound - Abdominal Major
Wound - Abdominal Minor
Wound - Vaginal
Wound - Vaginal Major
Wound - Vaginal Minor

Synthetic at midurethra

Acute Bleeding

**American Urological Association, Inc.
SUI Guidelines Panel**

**Complications for Groups with Uniform SUI
Treatment - with or without Prolapse RX**

Bladder Injury
Bowel Injury
Death
Dysuria
Fistula
Hematoma
Infection
Infection - Local Extension
Infection - Systemic
Infection - UTI
Infection - Wound
MI
None (per Author)
Other Complications
PE/DVT
Removal of Foreign Body - other
Sexual Dysfunction
Transfusion
Urethral Erosion
Vascular Injury
Wound
Wound - Abdominal
Wound - Abdominal Major
Wound - Abdominal Minor
Wound - Vaginal
Wound - Vaginal Major
Wound - Vaginal Minor

Transvaginal Cooper's Ligament Suspension

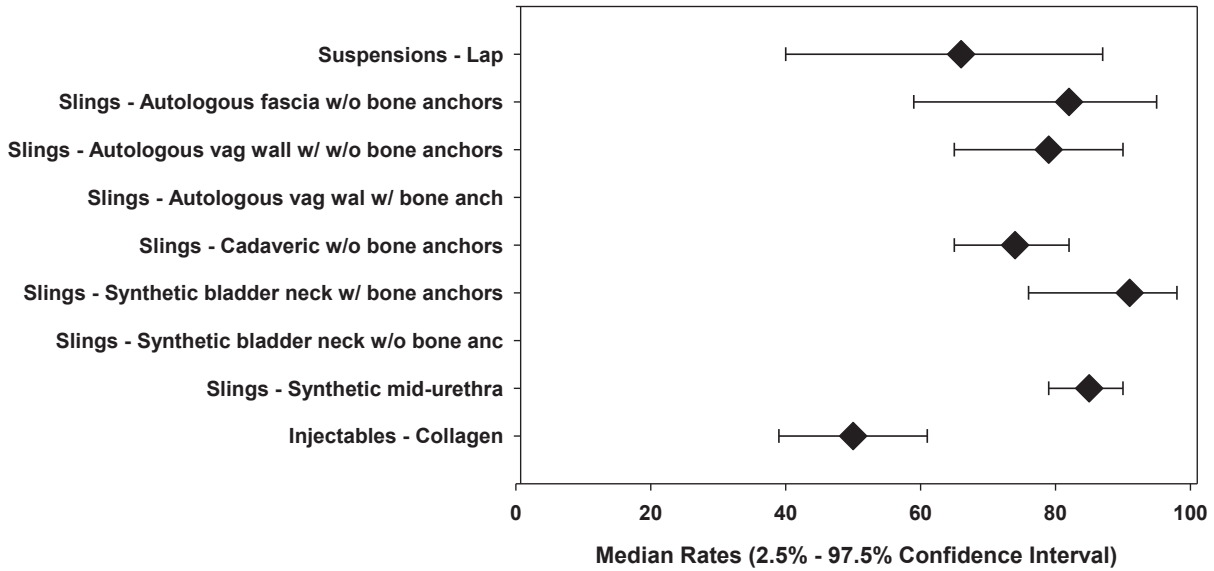
Death
Hematoma
None (per Author)
Other Complications
Wound - Vaginal Minor

Xenograft without bone anchors

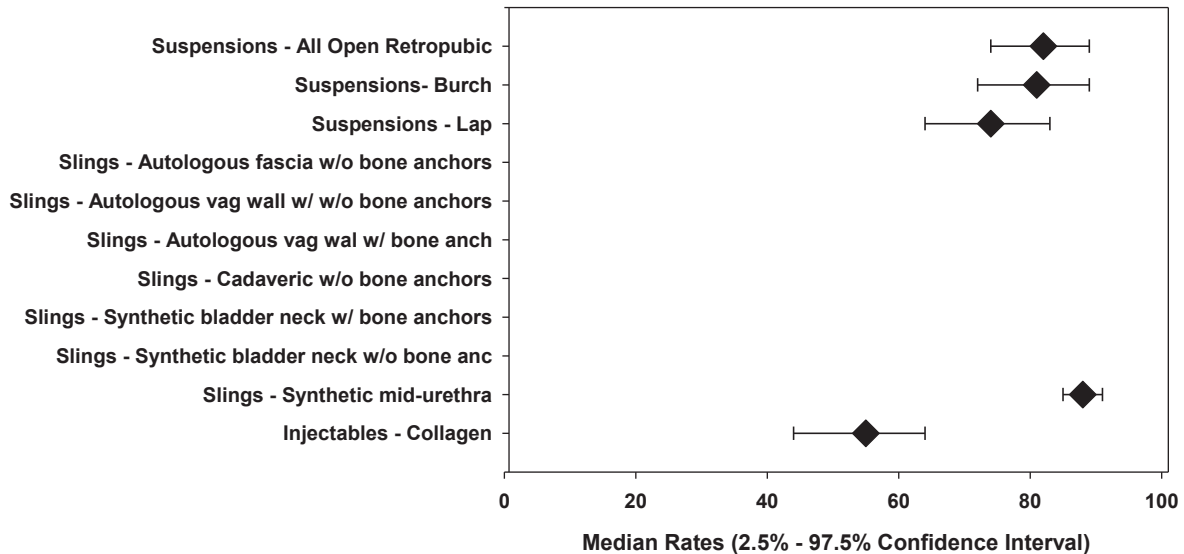
Wound - Abdominal Major
Wound - Vaginal Major
Wound - Vaginal Minor

Appendix A18 – Outcomes Graphs

No Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 12-23 Mos

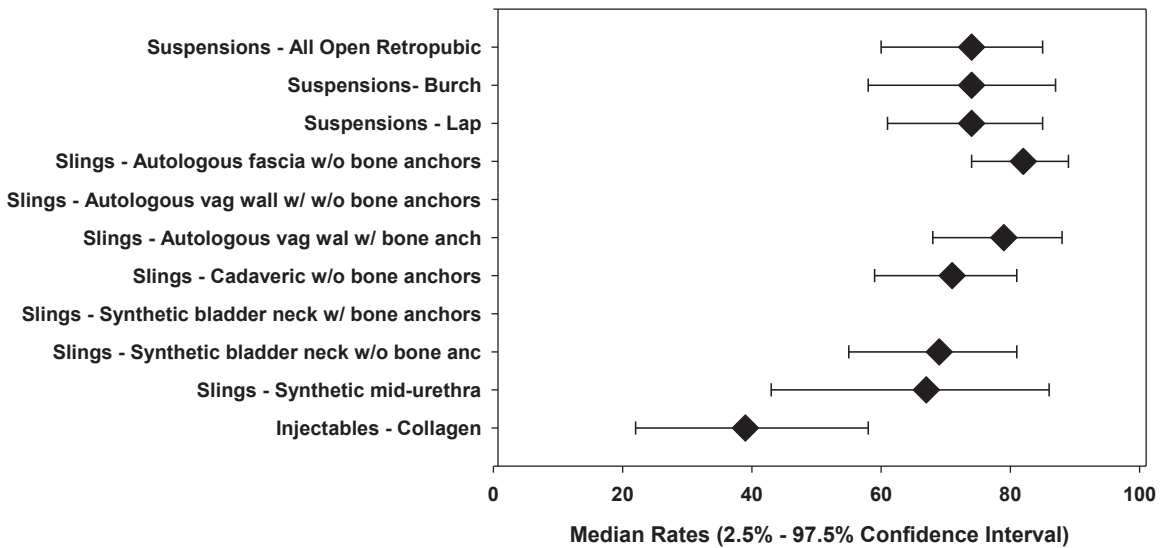


No Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 12-23 Mos

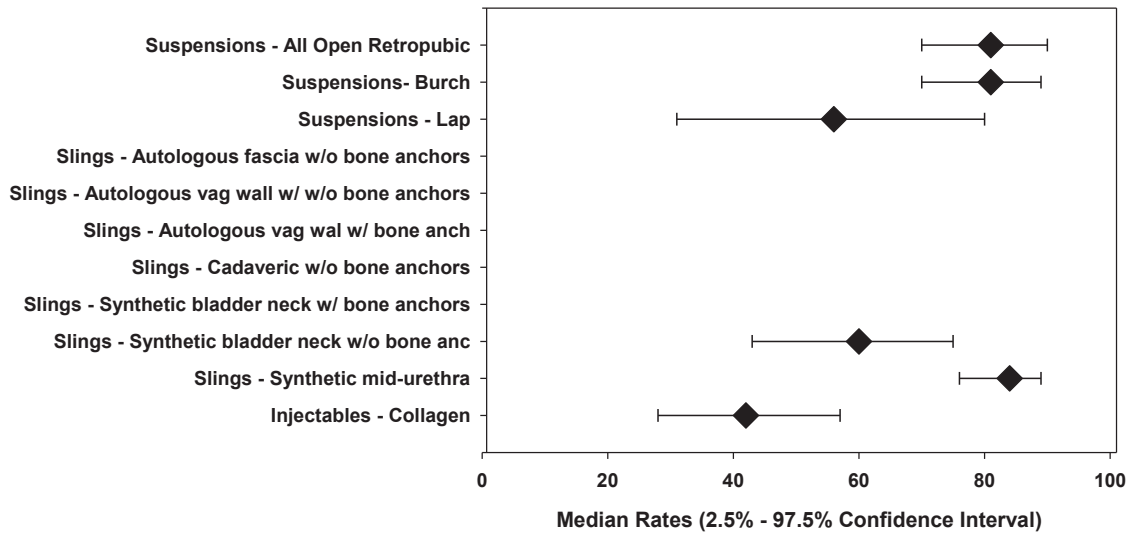


Appendix A18 – Outcomes Graphs

No Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 24-47 Mos

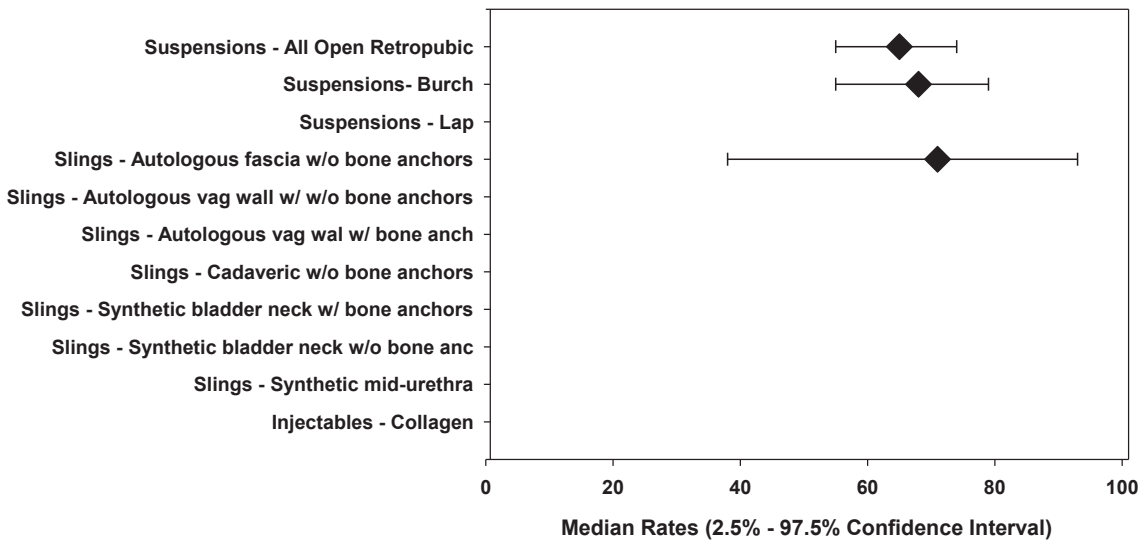


No Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 24-47 Mos

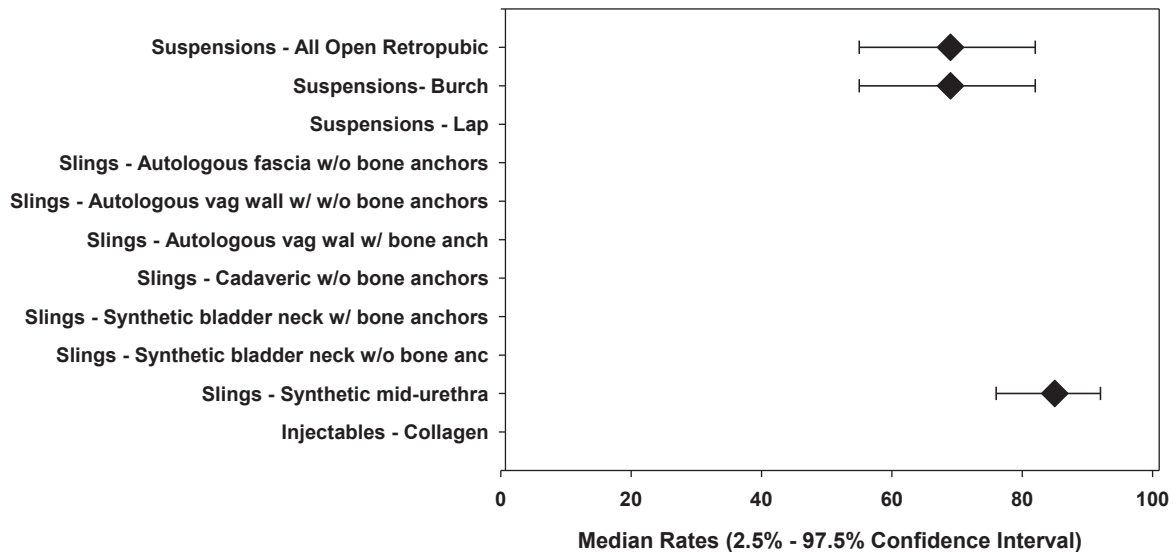


Appendix A18 – Outcomes Graphs

No Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 48+ Mos

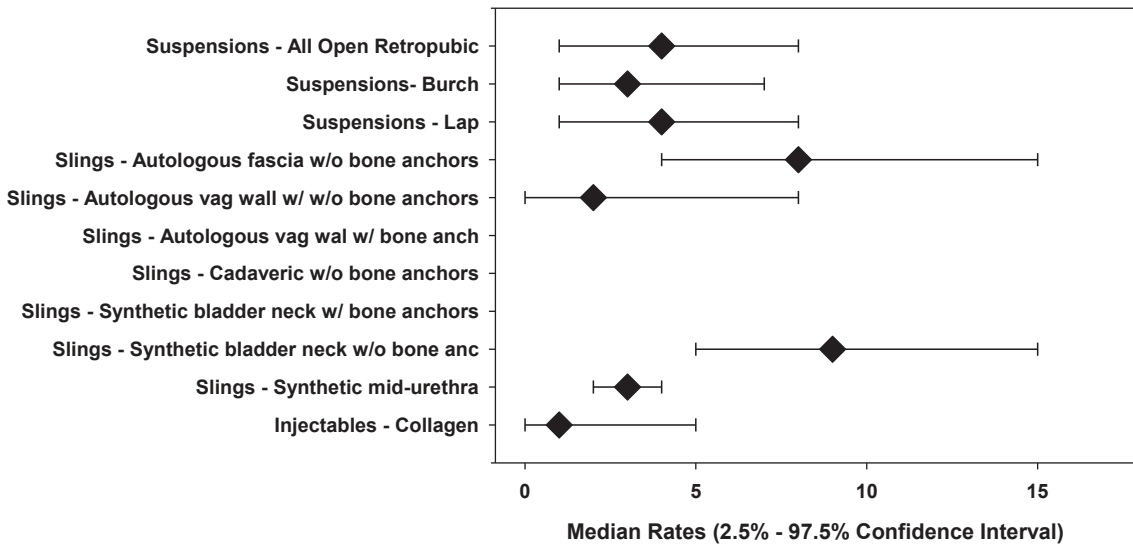


No Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 48+ Mos

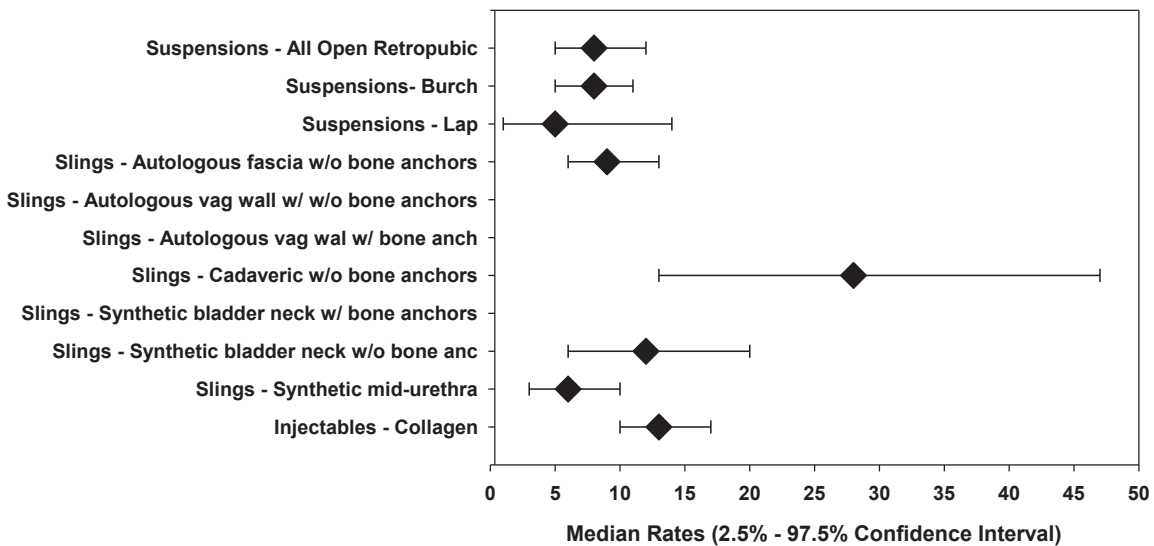


Appendix A18 – Outcomes Graphs

No Prolapse Patients: Retention > 28 days or Intervention

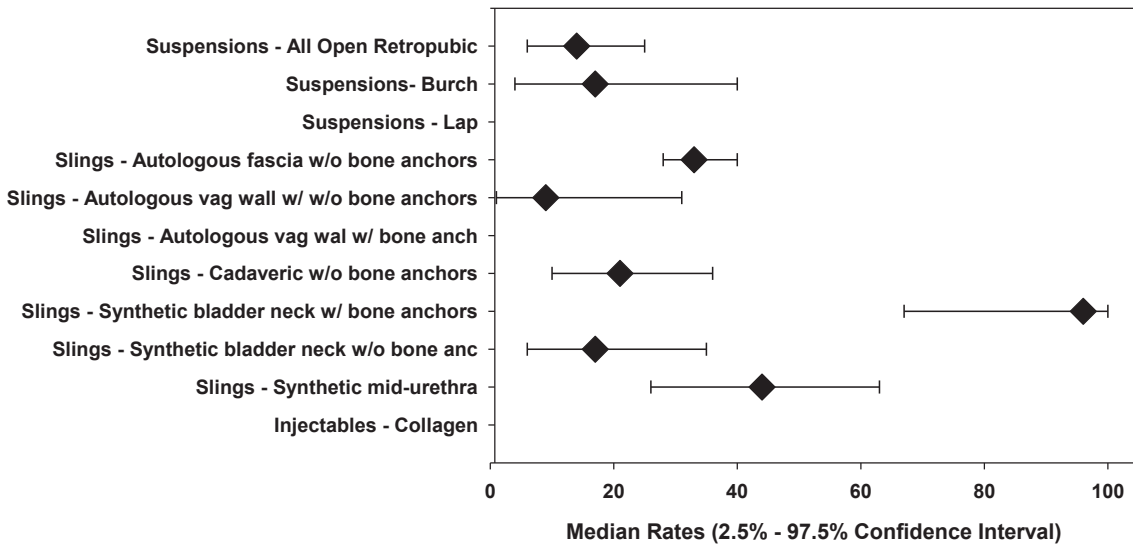


No Prolapse Patients: Urgency Urge Incontinence - New Onset

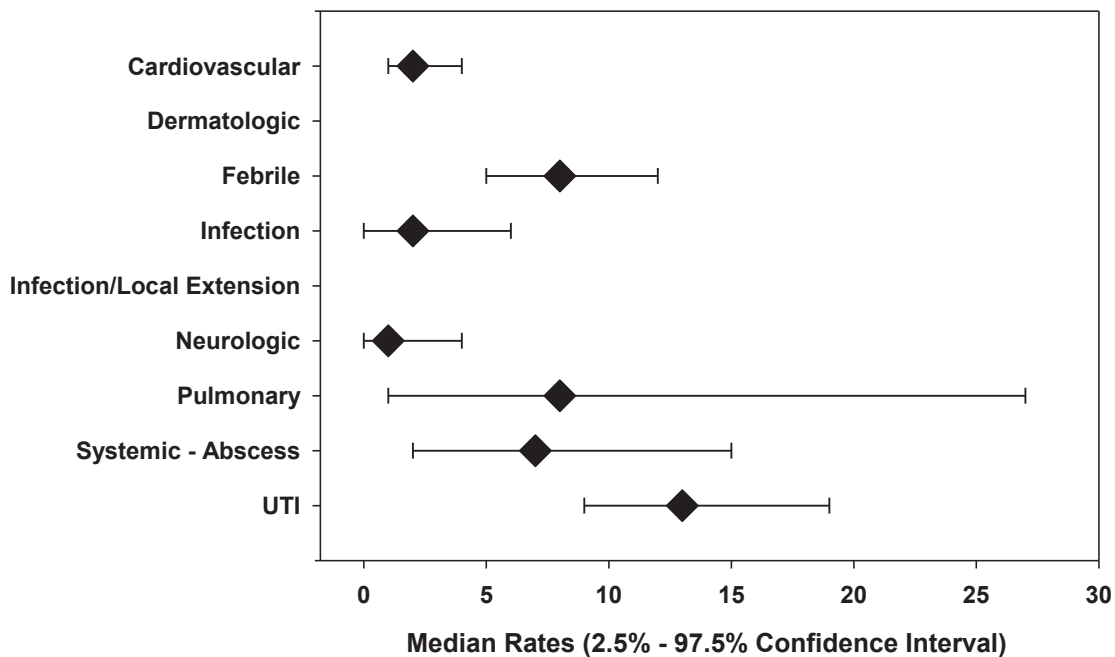


Appendix A18 – Outcomes Graphs

No Prolapse Patients: Urgency Urge Incontinence - Pre-Existing

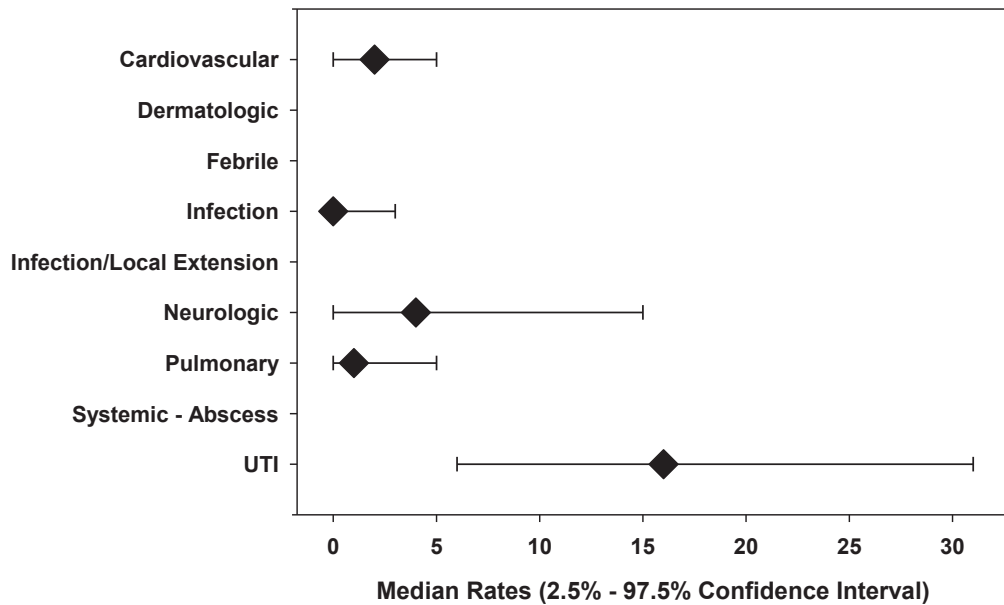


No Prolapse Patients: General Medical Complications All Retropubic Suspensions

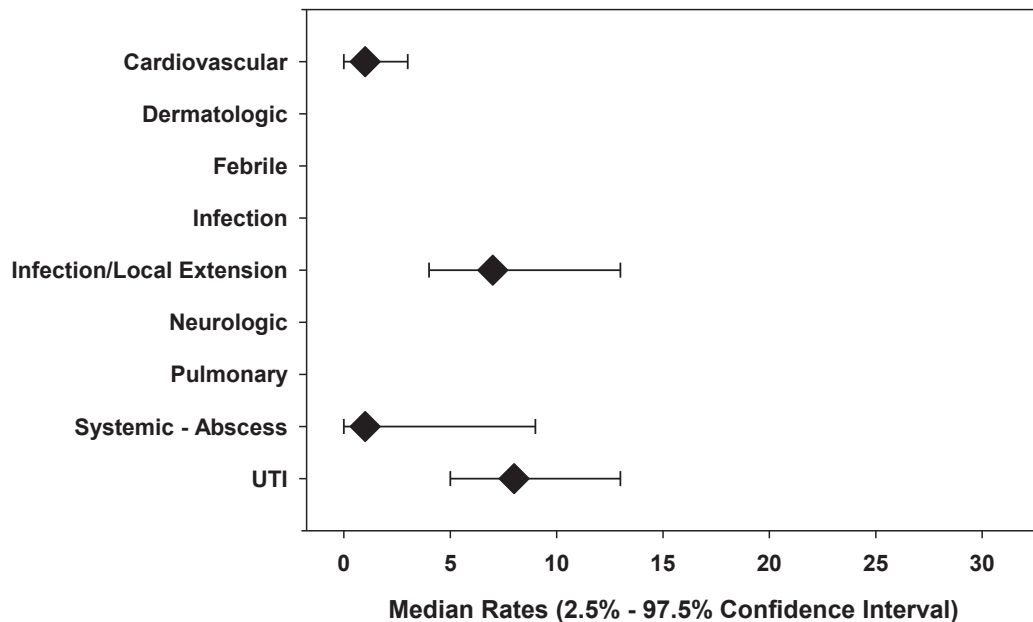


Appendix A18 – Outcomes Graphs

No Prolapse Patients: General Medical Complications Autologous Fascia Sling

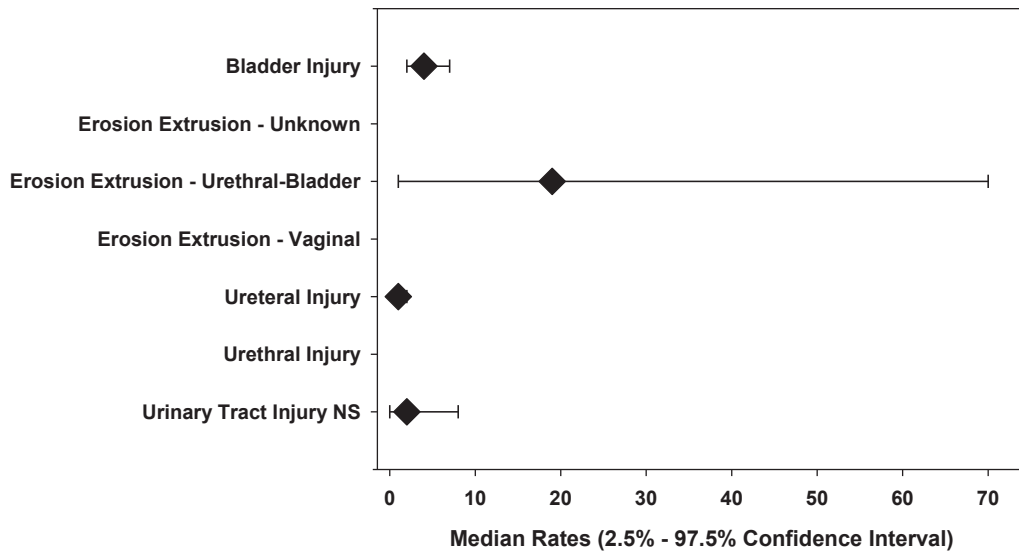


No Prolapse Patients: General Medical Complications Synthetic at Mid-Urethra

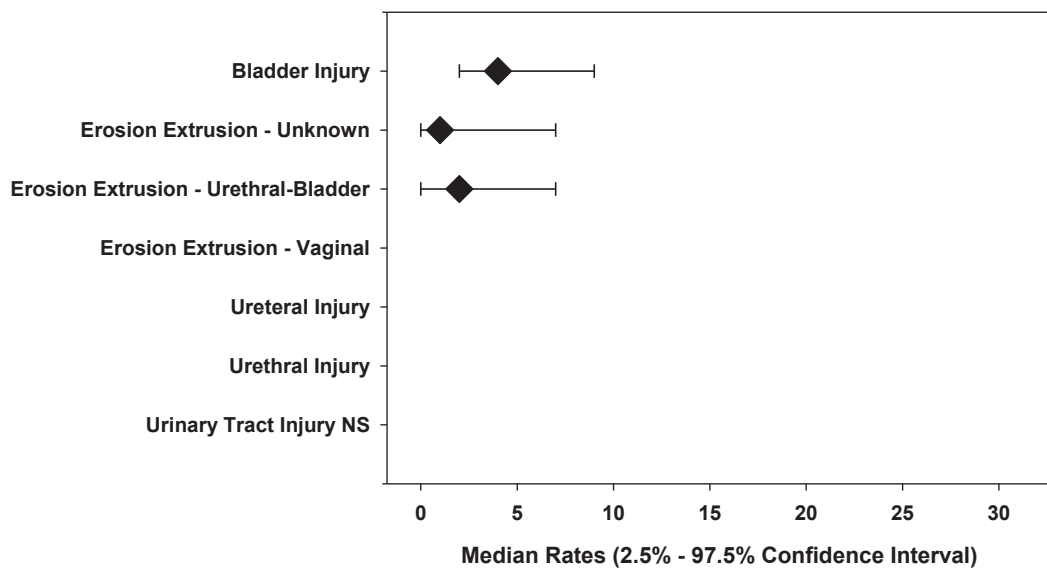


Appendix A18 – Outcomes Graphs

No Prolapse Patients: Operative Complications All Retropubic Suspensions

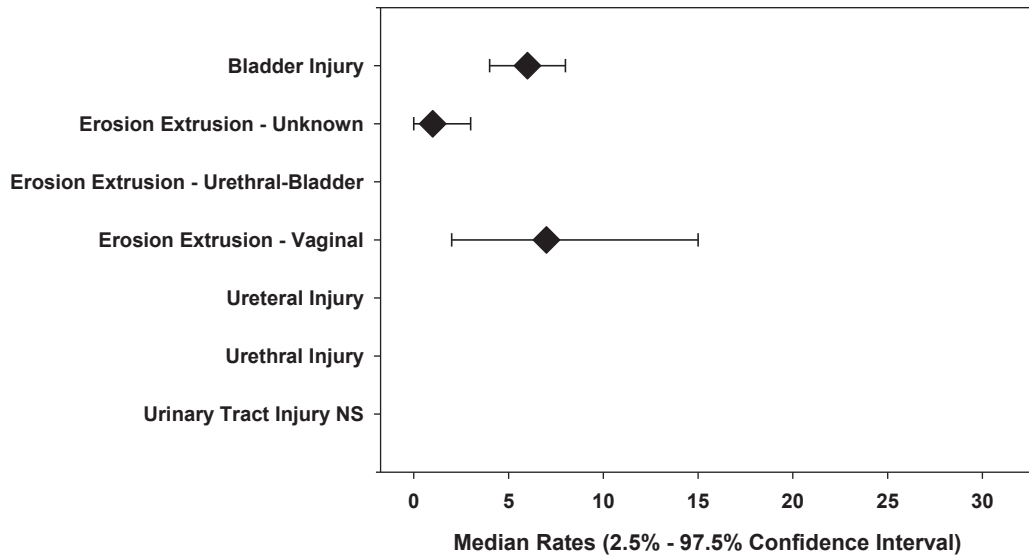


No Prolapse Patients: Operative Complications Autologous Fascia Sling

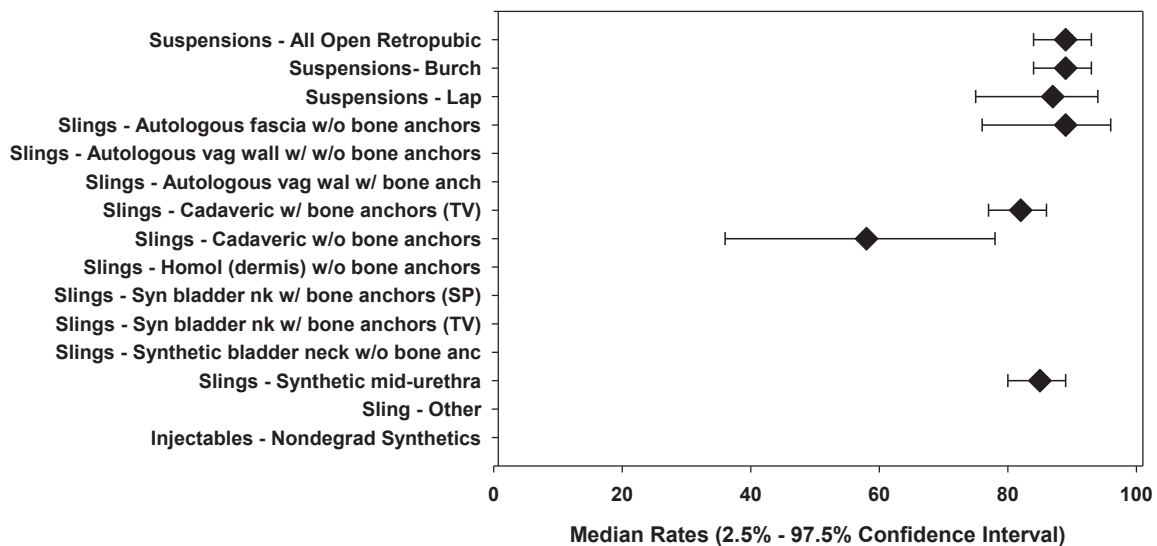


Appendix A18 – Outcomes Graphs

No Prolapse Patients: Operative Complications Synthetic at Mid-Urethra

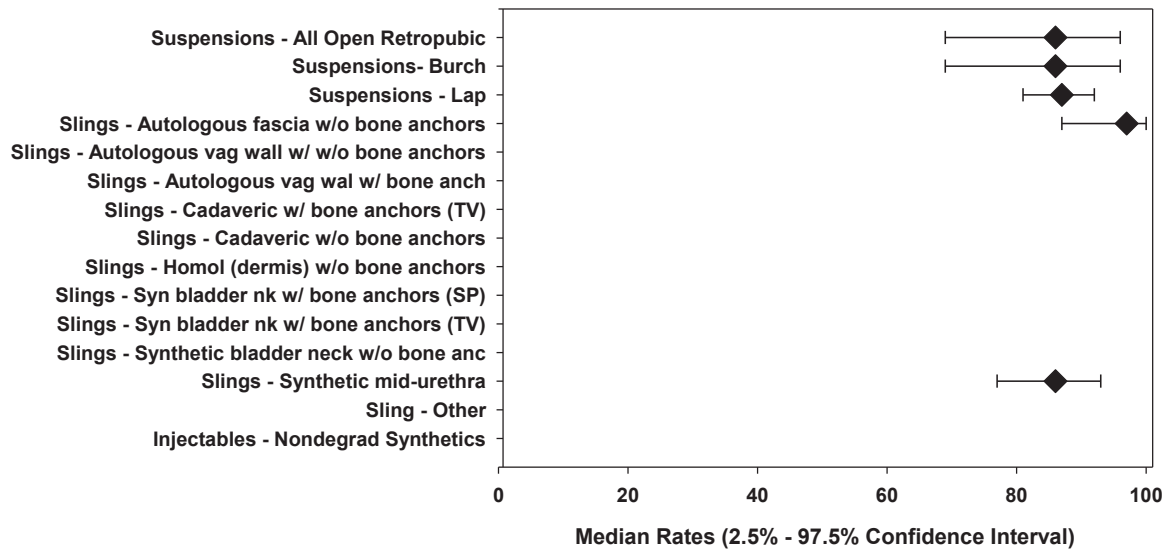


Any Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 12-23 Mos

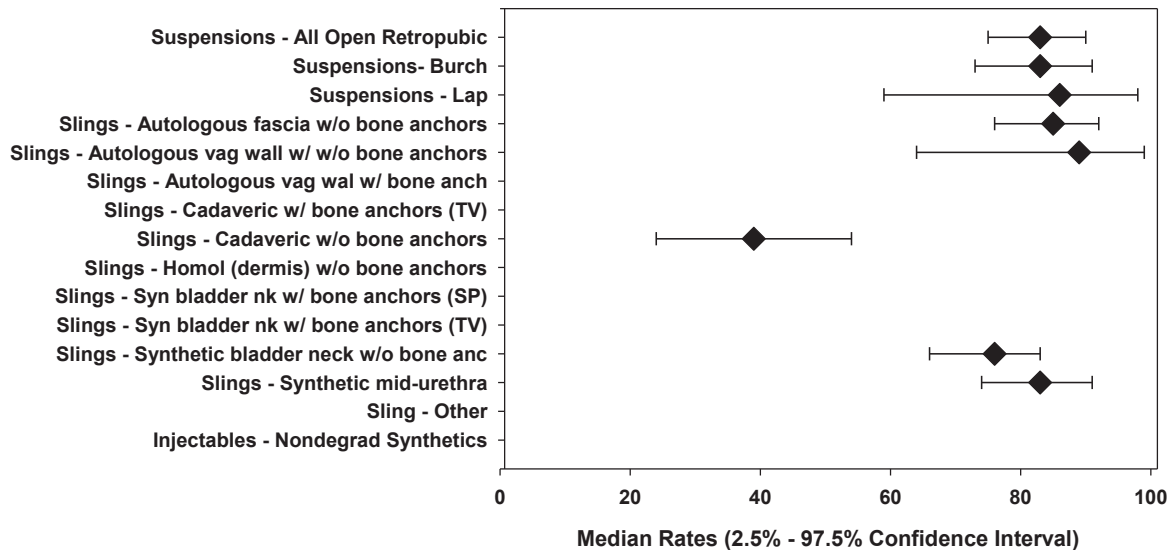


Appendix A18 – Outcomes Graphs

Any Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 12-23 Mos

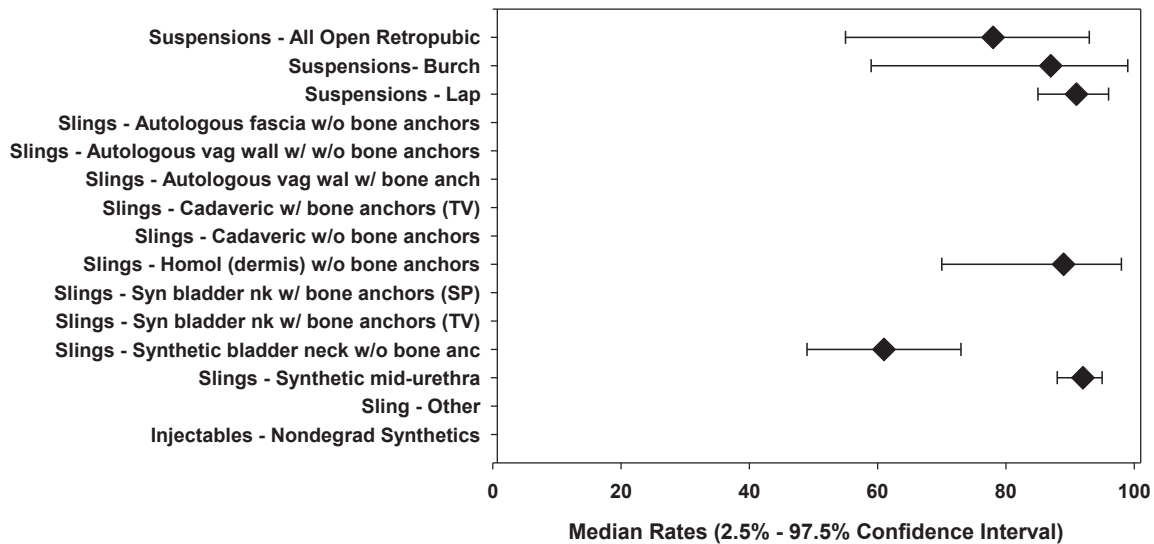


Any Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 24-47 Mos

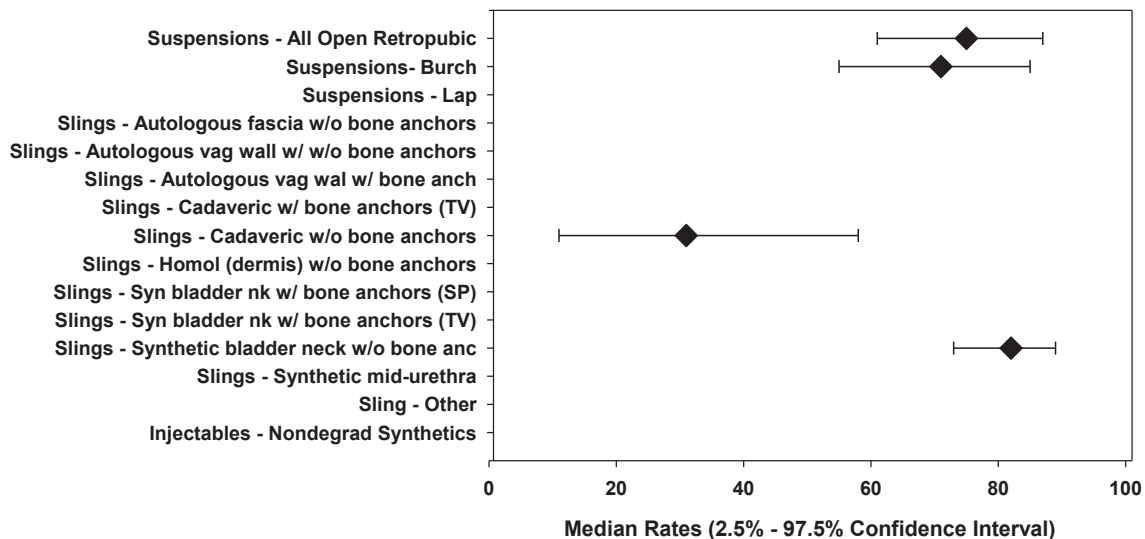


Appendix A18 – Outcomes Graphs

Any Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 24-47 Mos

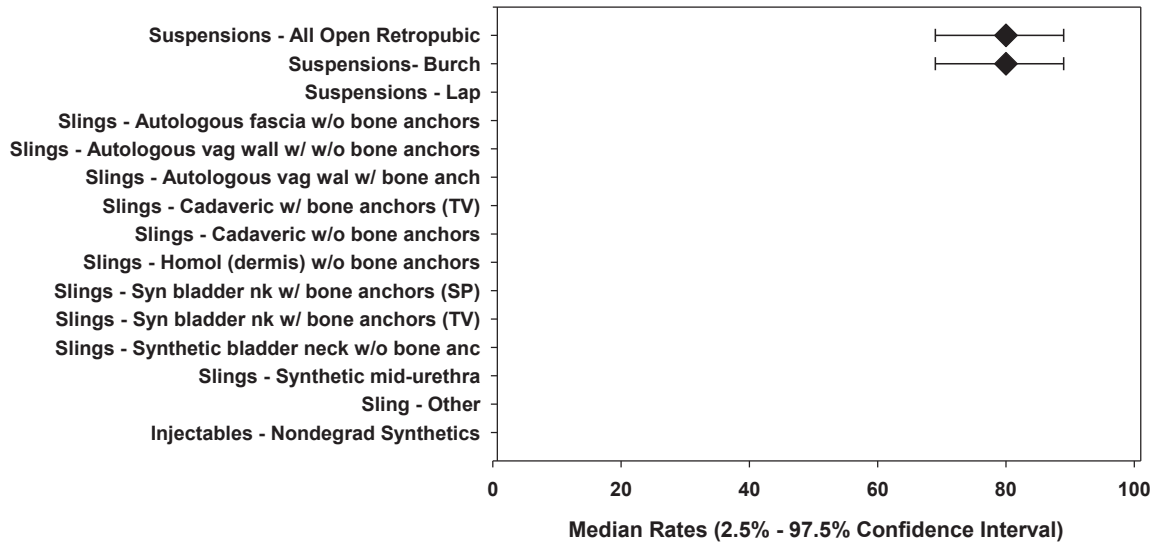


Any Prolapse Patients: Median Cure/Dry Rate Subjective Evaluation - 48+ Mos

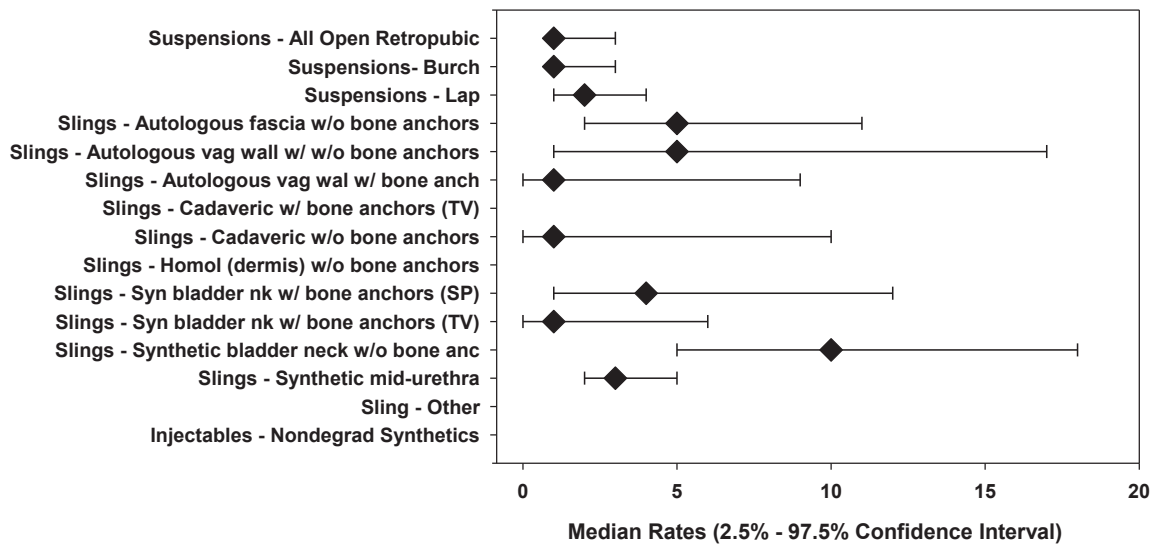


Appendix A18 – Outcomes Graphs

Any Prolapse Patients: Median Cure/Dry Rate Objective Evaluation - 48+ Mos

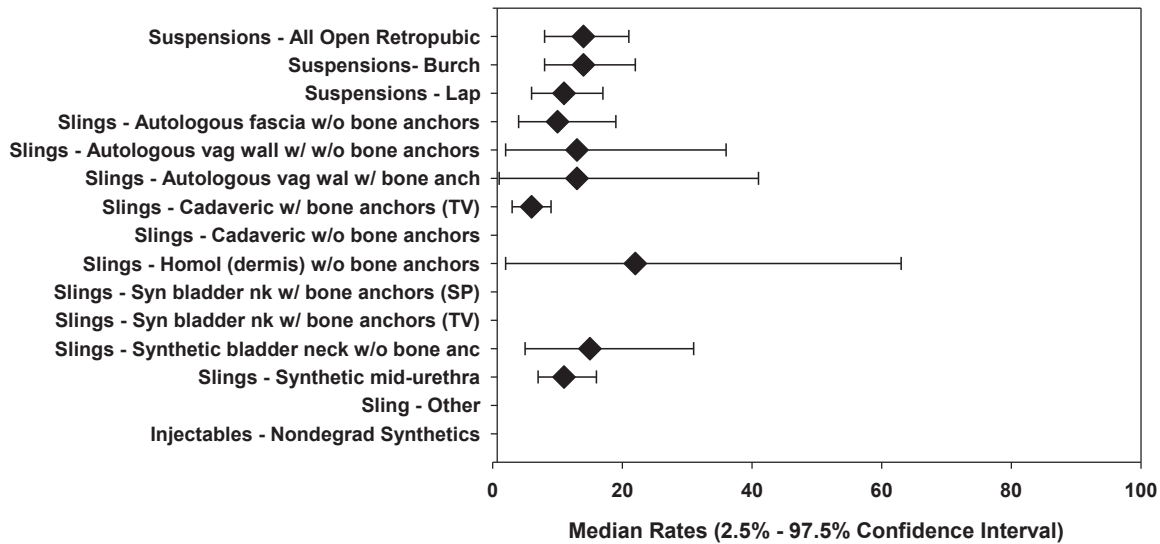


Any Prolapse Patients: Retention > 28 days or Intervention

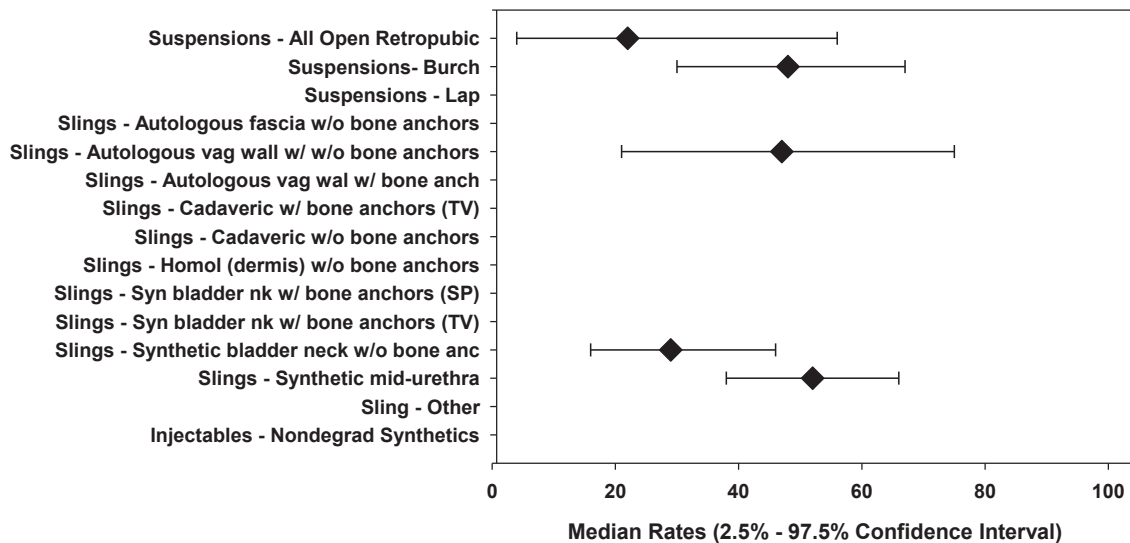


Appendix A18 – Outcomes Graphs

Any Prolapse Patients: Urgency Urge Incontinence - New Onset

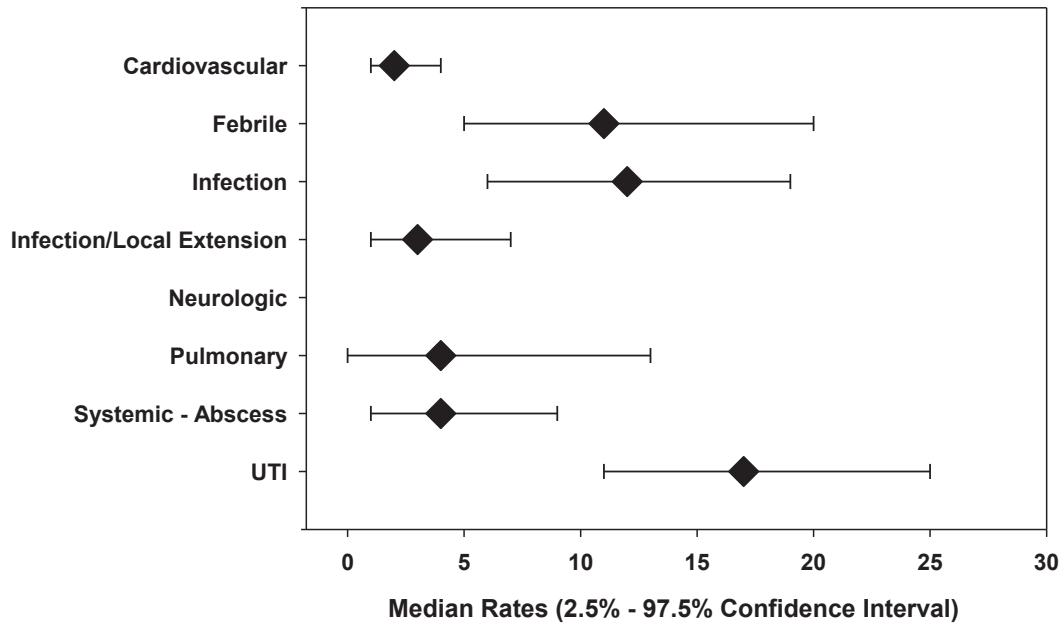


Any Prolapse Patients: Urgency Urge Incontinence - Pre-Existing

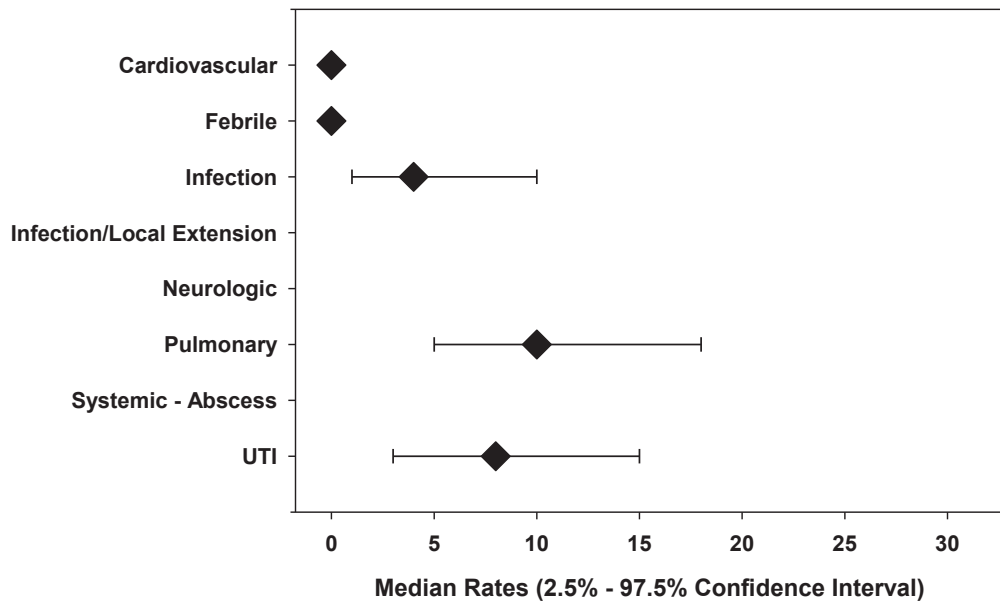


Appendix A18 – Outcomes Graphs

Any Prolapse Patients: General Medical Complications All Retropubic Suspensions

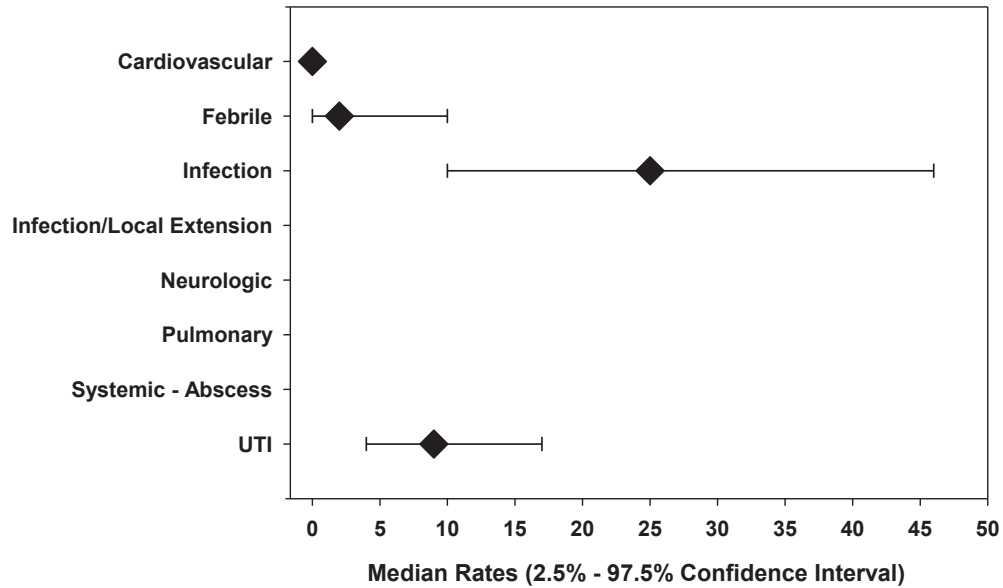


Any Prolapse Patients: General Medical Complications Autologous Fascia Sling

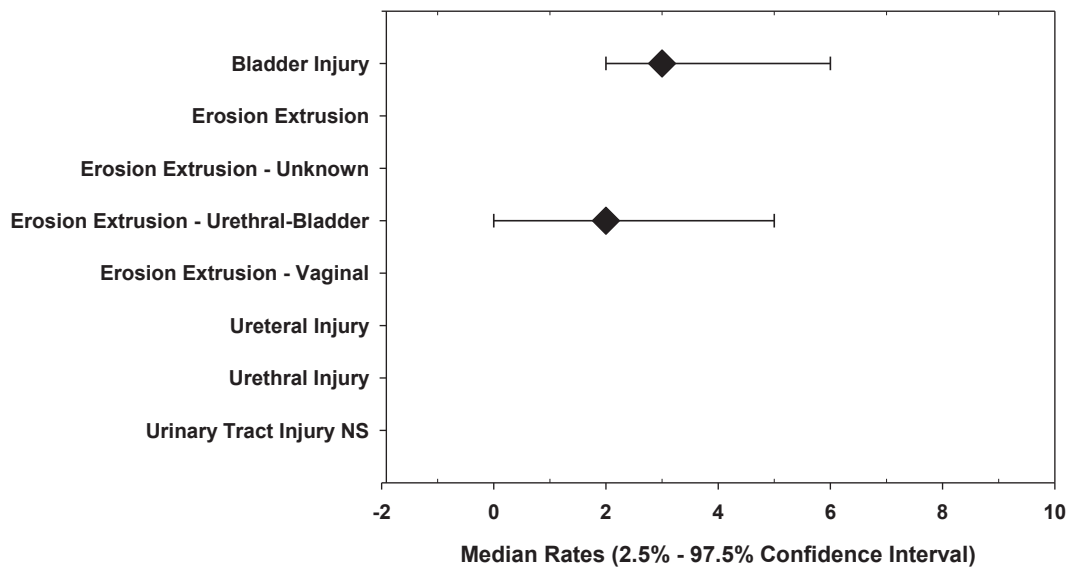


Appendix A18 – Outcomes Graphs

Any Prolapse Patients: General Medical Complications Synthetic at Bladder Neck

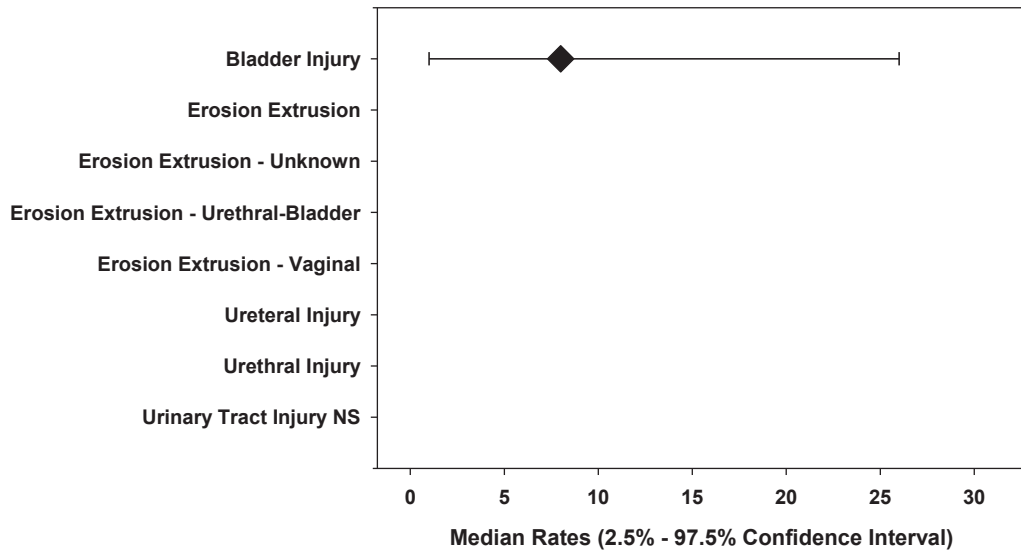


Any Prolapse Patients: Operative Complications All Retropubic Suspensions

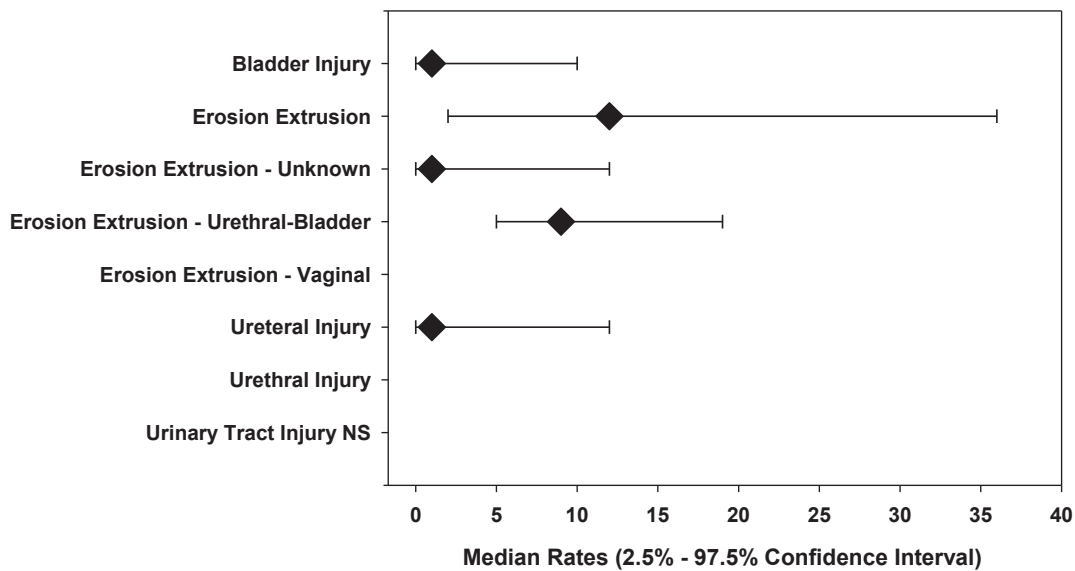


Appendix A18 – Outcomes Graphs

Any Prolapse Patients: Operative Complications Autologous Fascia Sling



Any Prolapse Patients: Operative Complications Synthetic at Bladder Neck



Appendix A18 – Outcomes Graphs

Any Prolapse Patients: Operative Complications Xenograft - Synthetic at Mid-Urethra

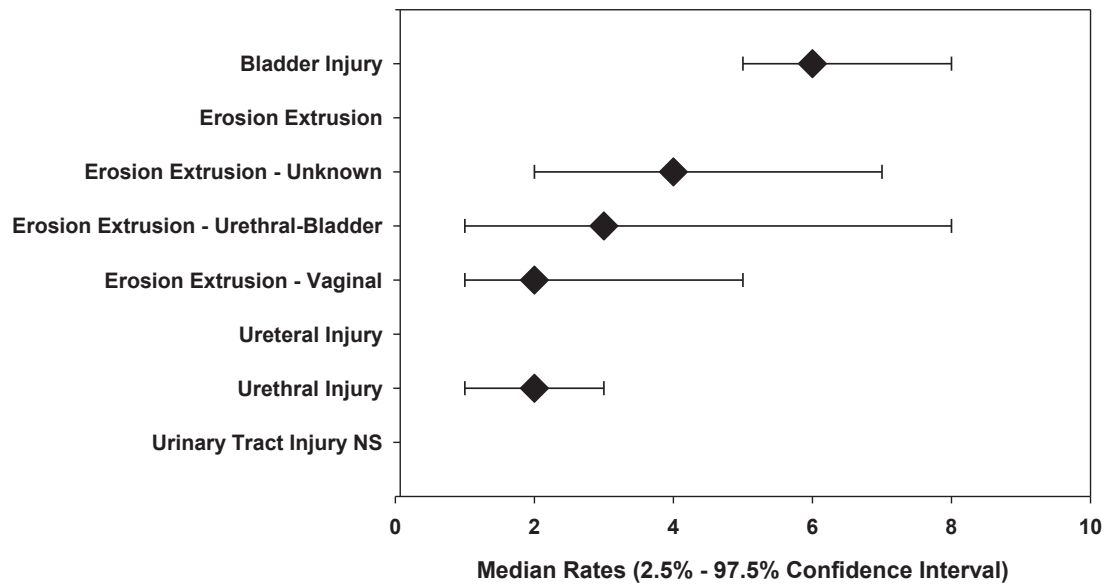


EXHIBIT J

UROGYNECOLOGY

Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis

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OBJECTIVE: Understanding the long-term comparative effectiveness of competing surgical repairs is essential as failures after primary interventions for stress urinary incontinence (SUI) may result in a third of women requiring repeat surgery.

STUDY DESIGN: We conducted a systematic review including English-language randomized controlled trials from 1990 through April 2013 with a minimum 12 months of follow-up comparing a sling procedure for SUI to another sling or Burch urethropepy. When at least 3 randomized controlled trials compared the same surgeries for the same outcome, we performed random effects model metaanalyses to estimate pooled odds ratios (ORs).

RESULTS: For midurethral slings (MUS) vs Burch, metaanalysis of objective cure showed no significant difference (OR, 1.18; 95% confidence interval [CI], 0.73–1.89). Therefore, we suggest either intervention; the decision should balance potential adverse events (AEs) and concomitant surgeries. For women considering pubovaginal sling vs Burch, the evidence favored slings for both subjective and objective cure. We recommend pubovaginal sling to maximize cure outcomes. For pubovaginal slings vs MUS, metaanalysis of subjective cure favored MUS (OR, 0.40; 95% CI,

0.18–0.85). Therefore, we recommend MUS. For obturator slings vs retropubic MUS, metaanalyses for both objective (OR, 1.16; 95% CI, 0.93–1.45) and subjective cure (OR, 1.17; 95% CI, 0.91–1.51) favored retropubic slings but were not significant. Metaanalysis of satisfaction outcomes favored obturator slings but was not significant (OR, 0.77; 95% CI, 0.52–1.13). AEs were variable between slings; metaanalysis showed overactive bladder symptoms were more common following retropubic slings (OR, 1.413; 95% CI, 1.01–1.98, $P = .046$). We recommend either retropubic or obturator slings for cure outcomes; the decision should balance AEs. For minislings vs full-length MUS, metaanalyses of objective (OR, 4.16; 95% CI, 2.15–8.05) and subjective (OR, 2.65; 95% CI, 1.36–5.17) cure both significantly favored full-length slings. Therefore, we recommend a full-length MUS.

CONCLUSION: Surgical procedures for SUI differ for success rates and complications, and both should be incorporated into surgical decision-making. Low- to high-quality evidence permitted mostly level-1 recommendations when guidelines were possible.

Key words: Burch urethropepy, midurethral sling, pubovaginal sling, stress urinary incontinence, single-incision sling

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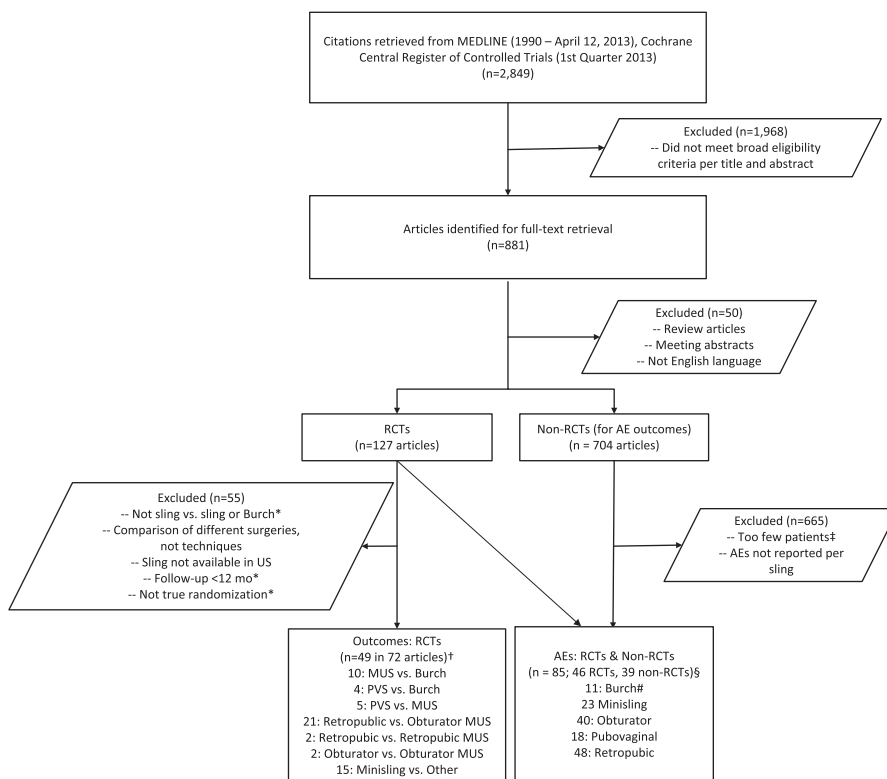
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FIGURE 1
Literature flow

PVS, pubovaginal slings.

*These studies were potentially eligible to be included for adverse event (AE) analyses; †Several studies had 3 arms and provided data for multiple comparisons; ‡For noncomparative studies, the following minimum sample size criteria were used: minisling obturator, $n \geq 120$; minisling retropubic, $n \geq 100$; obturator midurethral sling (MUS), $n \geq 1000$; pubovaginal fascial, $n \geq 300$; pubovaginal synthetic, $n \geq 120$; retropubic MUS, $n \geq 1000$; §Several studies reported on ≥ 2 slings; ¶Only from randomized controlled trials (RCTs).

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Data sources and searches

We searched MEDLINE and Cochrane Central Register for Controlled Trials from Jan. 1, 1990 through April 12, 2013 (Figure 1). We excluded older studies because the TVT was not available in the United States prior to this. Search terms included “urinary incontinence,” “urgency,” “sling,” “obturator,” “retropubic,” “pubovaginal,” “vaginal tape,” “urologic surgical procedures” (instrumentation or adverse effects), and related terms. The search was limited to comparative studies, cohort studies, and systematic reviews. The search was further limited to human and English-language studies. Meeting abstracts were excluded. Any review articles obtained in this search were excluded after reference lists were reviewed and articles not originally in the search were obtained. Study authors were not contacted.

Twelve reviewers independently double-screened the abstracts using the computerized screening program Abstrackr (Tufts Medical Center, Boston, MA).⁴ To establish relevance and consensus among reviewers, all 12 screened and achieved consensus on an initial batch of 300 abstracts. Potentially relevant full-text articles were also independently double-screened by 12 reviewers.

Study selection

For the principal evaluation of outcomes, we included peer-reviewed randomized controlled trials (RCTs) with at least 12 months of follow-up (Table 1). Trials were excluded from outcomes analysis for poor randomization schemes, such as alternate assignment of patients or assignment based on day of the week or birth date. We included RCTs that compared ≥ 2 sling procedures or a sling procedure to Burch urethropexy performed in adult women for SUI. Studies that compared Burch urethropexy to any other surgery were excluded. Bulking injections were excluded because they are not similar enough to sling surgeries regarding cure, perioperative data, or AEs. When a study included 3 arms, it was analyzed as multiple 2-arm comparisons. For the evaluation of AEs we

Stress urinary incontinence (SUI), or the involuntary loss of urine with activity such as coughing, laughing, and sneezing, is present in 15-80% of women.¹ Options for treating SUI include physical therapy, pessaries, urethral bulking injections, and surgery. Surgery traditionally consisted of Burch urethropexy or pubovaginal sling. Since 1996, when Ulmsten et al² published the initial paper about retropubic tension-free vaginal tape (TVT), the use of synthetic midurethral slings (MUS) has grown to become the most common surgery performed for SUI in women.³ This type of surgery has evolved to also include options of obturator passage and smaller, single-incision synthetic slings (eg, “minislings”).

The decision of which SUI procedure to perform can include suture-only, native

tissue, mesh, laparoscopic, open incisions, small incisions, or single-incision surgery. Many studies have compared these options. The primary aim of our work was to utilize systematic review and meta-analysis methodology to compare objective and subjective cure rates in adult women with SUI between these different surgeries. The secondary outcomes were to compare surgical methods by quality-of-life measures, sexual function, and perioperative and adverse event (AE) data.

MATERIALS AND METHODS

The Society of Gynecologic Surgeons Systematic Review Group includes members with clinical and surgical expertise on female SUI and in the conduct of systematic reviews and guideline development. This project was considered exempt from institutional review board approval.

TABLE 1
Randomized controlled trials included in systematic review

Study	Study quality ^f	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
MUS vs Burch												
Bai et al, ⁹ 2005 ^a	B	Retropubic MUS (TVT)	Burch	31	33	12 mo	X			X		
Bandarian et al, ¹⁰ 2011	C	Obturator MUS (TOT, unspecified)	Burch	31	31	25 mo mean		X	X	X		
Foote et al, ¹¹ 2006	C	Retropubic MUS (SPARC)	Laparoscopic Burch	49	48	24 mo	X	X	X	X		
Liapis et al, ¹² 2002	C	Retropubic MUS (TVT)	Burch	36	35	24 mo	X	X	X	X		
Paraiso et al, ¹³ 2004 ^b	B	Retropubic MUS (TVT)	Laparoscopic Burch	36	36	21 mo	X	X	X	X	X	
Persson et al, ¹⁴ 2002	B	Retropubic MUS (TVT)	Laparoscopic Burch	38	33	12 mo	X	X	X	X		
Sivasslioglu et al, ¹⁵ 2007	A	Obturator MUS (Safyre T)	Burch	49	51	24 mo	X	X	X	X		
Télez Martínez-Fomés et al, ¹⁶ 2009	B	Retropubic MUS (TVT)	Burch	24	25	36 mo	X	X	X	X	X	
Wang and Chen, ¹⁷ 2003	B	Retropubic MUS (TVT)	Burch	49	49	22 mo	X	X	X	X		
Ward et al, ¹⁸ 2002 ^c	B	Retropubic MUS (TVT)	Burch	169	175	5 y	X		X	X	X	X
PVS vs Burch												
Albo et al, ¹⁹ 2007 (SISTER Trial) ^d	A	PVS (autologous fascia)	Burch	326	329	24 mo	X	X	X	X	X	
Bai et al, ⁹ 2005 ^a	B	PVS (autologous fascia)	Burch	28	33	12 mo	X			X		
Culligan et al, ²⁰ 2003 ^e	B	PVS (Gore-Tex)	Burch	17	19	73 mo	X		X	X		
Enzelsberger et al, ²¹ 1996	C	PVS (dura mater)	Burch	36	36	36 mo	X		X	X		
PVS vs MUS												
Amaro et al, ²² 2009	C	PVS (autologous fascia)	Retropubic MUS (TVT)	21	20	44 mo		X	X	X	X	
Bai et al, ⁹ 2005 ^a	B	PVS (autologous fascia)	Retropubic MUS (TVT)	28	31	12 mo	X			X		
Guerrero et al, ²³ 2010 ^f	B	PVS (autologous fascia)	Retropubic MUS (TVT)	79	50	12 mo		X	X	X	X	
Sharifiaghdas and Mortazavi, ²⁴ 2008	B	PVS (autologous fascia)	Retropubic MUS (TVT)	52	48	40 mo	X	X	X	X	X	
Tcherniakovsky et al, ²⁵ 2009	C	PVS (autologous fascia)	Obturator MUS (Safyre T)	20	21	12 mo	X		X	X		
Retropubic vs obturator MUS												
Aniuliene, ²⁶ 2009	C	TVT	TVT-0	114	150	12 mo		X	X	X		
Araco et al, ²⁷ 2008	B	TVT	TVT-0	108	100	12 mo	X		X	X	X	
Ballester et al, ²⁸ 2012 ^g	B	Retropubic ISTOP	Transobturator ISTOP	42	46	48 mo	X	X	X	X	X	

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(continued)

TABLE 1

Randomized controlled trials included in systematic review (continued)

Study	Study quality ^f	Intervention	Comparator	n _i intervention	n _c comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
Barber et al, ²⁹ 2008 ^h	A	TVT	Monarc	88	82	18 mo	X	X	X	X	X	X
Deffieux et al, ³⁰ 2010	A	TVT	TVT-0	75	74	24 mo	X	X	X	X	X	X
El-Hefnawy et al, ³¹ 2010	C	TVT	Obturator MUS (unspecified)	19	21	20 mo	X	X	X	X		
Freeman et al, ³² 2011	A	TVT	Monarc	93	100	12 mo		X	X	X	X	X
Karateke et al, ³³ 2009	A	TVT	TVT-0	83	84	14 mo		X	X	X	X	X
Krofta et al, ³⁴ 2010	A	TVT	TVT-0	149	151	12 mo		X	X	X	X	X
Liapis et al, ³⁵ 2006	C	TVT	TVT-0	46	43	12 mo		X	X	X		
Richter et al, ¹ 2010 (TOMUS Trial) ^j	A	TVT	Obturator MUS (TVT-0 or Monarc)	298	299	24 mo	X	X	X	X	X	X
Rinne et al, ³⁶ 2008 ^l	A	TVT	TVT-0	136	131	36 mo	X	X	X	X	X	X
Ross et al, ³⁷ 2009	B	Retropubic MUS (Advantage)	Obturator MUS (Obtryx)	105	94	12 mo	X	X	X	X	X	X
Scheiner et al, ³⁸ 2012 ^k	B	TVT	Monarc	80	40	12 mo		X	X	X	X	X
Scheiner et al, ³⁸ 2012 ^k	B	TVT	TVT-0	80	40	12 mo		X	X	X	X	X
Schierlitz et al, ³⁹ 2008 ^l	B	TVT	Monarc	82	82	36 mo		X	X	X	X	X
Teo et al, ⁴⁰ 2011	B	TVT	TVT-0	66	61	12 mo		X	X	X	X	X
Wang F et al, ⁴¹ 2010	A	TVT	Obturator MUS (out-to-in)	70	70	12 mo	X	X	X	X	X	X
Wang W et al, ⁴² 2009	B	TVT	TVT-0	160	155	36 mo		X	X	X		
Wang YJ et al, ⁴³ 2011 ^m	B	TVT	TVT-0	32	36	12 mo		X	X	X		
Zullo et al, ⁴⁴ 2007 ⁿ	B	TVT	TVT-0	35	37	5 y	X	X	X	X	X	X
Retropubic MUS vs retropubic MUS												
Andonian et al, ⁴⁵ 2005	B	SPARC	TVT	41	43	12 mo		X	X	X		
Tseng et al, ⁴⁶ 2005	B	SPARC	TVT	31	31	24 mo		X	X	X		
Obturator MUS vs obturator MUS												
Abdel-Fattah et al, ⁴⁷ 2010 (E-TOT Trial) ^o	B	ARIS TOT (out-to-in)	TVT-0 (in-to-out)	171	170	12 mo		X	X	X	X	X
Scheiner et al, ³⁸ 2012 ^k	B	Monarc	TVT-0	40	40	12 mo		X	X	X	X	X

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(continued)

TABLE 1
Randomized controlled trials included in systematic review (continued)

Study	Study quality ^f	Intervention	Comparator	n, intervention	n, comparator	Follow-up duration	OC	SC	Po	AE	QoL	SF
Minisling vs any other sling												
Andrada Hamer et al, ⁴⁸ 2013	B	TVT-Secur H	TVT	64	69	12 mo	X	X	X	X		
Barber et al, ⁴⁹ 2012	A	TVT-Secur U	TVT	136	127	12 mo	X	X	X	X	X	X
Hinoul et al, ⁵⁰ 2011	A	TVT-Secur H	TVT-O	97	98	12 mo	X	X	X	X	X	
Hota et al, ⁵¹ 2012	A	TVT-O	TVT-Secur	44	42	12 mo	X	X	X	X	X	
Kim et al, ⁵² 2010	B	TVT-Secur U	TVT-Secur H	53	62	12 mo	X	X	X	X	X	X
Lee et al, ⁵³ 2010	A	TVT-Secur U	TVT-Secur H	165	165	12 mo	X	X	X	X	X	X
Masata et al, ⁵⁴ 2012 ^p	A	TVT-Secur U	TVT-O	65	68	24 mo	X	X	X	X	X	
Masata et al, ⁵⁴ 2012 ^p	A	TVT-Secur H	TVT-O	64	68	24 mo	X	X	X	X	X	
Masata et al, ⁵⁴ 2012 ^p	A	TVT-Secur U	TVT-Secur H	65	64	24 mo	X	X	X	X	X	
Oliveira et al, ⁵⁵ 2011 ^q	C	TVT-Secur H	TVT-O	30	30	12 mo	X		X	X		
Oliveira et al, ⁵⁵ 2011 ^q	C	MiniArc	TVT-O	30	30	12 mo	X		X	X		
Oliveira et al, ⁵⁵ 2011 ^q	C	TVT-Secur H	MiniArc	30	30	12 mo	X		X	X		
Tommaselli et al, ⁵⁶ 2010	B	TVT-Secur H	TVT-O	42	42	12 mo	X		X	X	X	
Wang YJ et al, ⁴³ 2011 ^m	B	TVT-Secur	TVT	34	32	12 mo	X		X	X		
Wang YJ et al, ⁴³ 2011 ^m	B	TVT-Secur	TVT-O	34	36	12 mo	X		X	X		

Advantage; Boston Scientific Corp., Natick, MA; Gore-Tex; Gore Medical, Flagstaff, AZ; ISTOP, CL Medical, Winchester, MA; MiniArc; AMS, Minnetonka, MN; Monarc; AMS; Obtryx; Boston Scientific Corp.; Satyre; Promedon, Cordoba, Argentina; SPARC; AMS; TVT-O; Ethicon Gynecare, Cincinnati, OH; TVT-Secur, Ethicon Gynecare.

AE, adverse event; MUS, midurethral sling; OC, objective cure; Po, subjective cure; PVS, pubovaginal sling; QoL, life-of-life outcomes; SC, subjective cure; SF, sexual function outcomes; TOMUS, Trial of Midurethral Slings; TVT, tension-free vaginal tape; TVT-O, tension-free vaginal tape obstructor.

^a 3-Arm trial comparing PVS (autologous fascia) vs TVT vs Burch; ^b Jelovsek et al⁵⁹ 2008; ^c Ward et al⁶⁰ 2004 and Ward et al⁶¹ 2008; ^d Temstetdt et al⁶² 2005; Temstetdt et al⁶³ 2008; Chai et al⁶⁴ 2009; Kraus et al⁶⁵ 2011; Brubaker et al⁶⁶ 2012; ^e Sand et al⁶⁷ 2000; ^f Trial also included PVS (Pelvic) arm (n = 72) that was not included as Pelvic is off market; ^g Darai et al⁶⁸ 2007 and David-Monflore et al⁶⁹ 2006; ^h Barber et al⁷⁰ 2008; ⁱ Albo et al⁷¹ 2012; Zyczynski et al⁷² 2012; ^j Laurikainen et al⁷⁴ 2007 and Palva et al⁷⁵ 2010; ^k 3-Arm trial comparing Monarc vs TVT vs TVT-O; ^l Schieritz et al⁷⁶ 2012 and De Souza et al⁷⁷ 2012; ^m 3-Arm trial comparing TVT-Secur vs TVT vs TVT-O; ⁿ Anglioli et al⁷⁸ 2010; ^o Abdel-Fattah et al⁷⁹ 2010 and Abdel-Fattah et al⁸⁰ 2012; ^p 3-Arm trial comparing TVT-Secur H vs TVT-Secur U vs TVT-O; ^q 3-Arm trial comparing TVT-O vs TVT-Secur H vs MiniArc; ^r A (good), B (fair), C (poor).

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TABLE 2

Categorization of outcomes analyzed from randomized controlled trials

Outcome category of interest	Specific outcomes collected
Objective cure	Cough stress test
	Pad testing
	Urodynamic stress incontinence
	Voiding diary data
Subjective cure	Sandvik Incontinence Severity Index
	International Consultation on Incontinence Questionnaire (ICIQ)
	Patient Global Impression of Improvement (PGI-I)
	Pelvic Floor Distress Inventory (PFDI)
	Urinary Distress Inventory (UDI)
	Bristol female lower urinary tract symptom (BFLUTS)
	Measures such as “better” or “satisfied”
	“Would recommend to a friend”
Perioperative outcomes	Met expectations
	Estimated blood loss, time to return to normal activity/work, operative time, hospital time, length of stay, length of use of catheter, pain
Quality of life or satisfaction	Kings Health Questionnaire (KHQ)
	Measures of activities of daily living
	Urinary Incontinence Quality-of-life Scale (I-QOL)
	Bristol female lower urinary tract symptom (BFLUTS)
	Pelvic Floor Impact Questionnaire/Incontinence Impact Questionnaire (PFIQ/IIQ)
	International Consultation on Incontinence Questionnaire (ICIQ)
	CONTILIFE (Quality-of-life Assessment Questionnaire Concerning Urinary Incontinence)
Sexual function	Bristol female lower urinary tract symptom (BFLUTS)
	Pelvic Organ Prolapse/Incontinence Sexual Questionnaire, IUGA-Revised (PISQ-IR)
	CONTILIFE (Quality-of-life Assessment Questionnaire Concerning Urinary Incontinence)
	Dyspareunia
	“Return to normal sex life”
Adverse events	Table 3

IUGA, International Urogynecology Association.

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surgery was not collected. Sling types of interest included MUS (retropubic, obturator), pubovaginal slings at the bladder neck (biologic, synthetic, or autologous), and minislings. All studies had to report results for cohorts (or study arms) of women who all received the same sling type (or Burch urethropexy); studies that combined women who received different sling types in their analyses were excluded. Studies that examined various aspects of surgical technique, anesthesia, or surgeon training were excluded if the same type of sling was used in each arm. Data were excluded if the surgical product used was not available in the United States as of April 2013.

Outcomes of interest from RCTs fell into 6 categories: objective cure, subjective cure, perioperative outcomes, quality of life or satisfaction, sexual function, and AEs (Table 2). Studies with non-randomized designs were included only for AEs. Information on cost was not collected.

Data extraction and quality assessment

Data were extracted by 1 of 12 reviewers using a standard data extraction form and confirmed by another; discrepancies were resolved by consensus. We extracted data on study characteristics, participant characteristics, funding source, details on the interventions, length of follow-up, outcomes of interest measured, and how these outcomes were assessed. After data extraction, the lead reviewer and methodologist categorized all outcomes extracted from the RCTs into the 6 outcome categories listed above. Two reviewers also categorized all AEs into 22 categories as listed in Table 3. The underlying data, together with additional extracted information, are accessible online at <http://srdr.ahrq.gov/> in the project Sling surgery for stress urinary incontinence in women: Society of Gynecologic Surgeons 2013.

We assessed the methodological quality of each RCT using predefined criteria from a 3-category system modified from the Agency for Healthcare Research and Quality.⁵ Studies were graded as good (A), fair (B), or poor (C)

also included trials excluded from RCT analysis, nonrandomized comparative studies, and cohort (pre-post) studies of any follow-up duration. Because of the volume of these studies, sample size limitations were placed to restrict the

number of studies to only those with the most patients and therefore highest potential for identifying a complication (Figure 1). Studies included for AEs had to evaluate at least 1 sling type, and information about any other comparator

TABLE 3

Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies^{1,9-57,59-117}

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Estimated blood loss >200 mL					
Obturator	4	0.22% (0.03–1.59%)	1	448	0.00–1.79%
Minisling	3	1.1% (0.5–1.9%)	10	888	0.00–3.68%
Retropubic	4	1.5% (1.0–2.1%)	33	2071	0.21–4.76%
Transfusion					
Burch	3	0.00% (0.00–7.73%)	0	105	0.00–0.00%
Obturator	6	0.17% (0.02–1.22%)	1	584	0.00–0.40%
Retropubic	13	0.40% (0.28–0.55%)	31	8105	0.00–4.00%
Minisling	5	0.51% (0.23–1.14%)	6	1177	0.00–0.74%
Pubovaginal	5	1.9% (0.9–3.2%)	10	515	0.00–5.17%
Hematoma					
Obturator	18	0.59% (0.35–0.89%)	17	2995	0.00–2.41%
Retropubic	25	0.88% (0.74–1.0%)	184	15,950	0.00–16.13%
Minisling	2	0.85% (0.21–3.44%)	2	236	0.74–1.00%
Burch	4	1.4% (0.6–2.6%)	8	542	0.00–5.71%
Pubovaginal	5	2.2% (1.2–3.4%)	14	677	0.00–5.17%
Dyspareunia					
Retropubic	2	0.00% (0.01–1.64%)	0	488	0.00–0.00%
Obturator	6	0.16% (0.02–1.14%)	1	624	0.00–0.40%
Minisling	11	0.74% (0.40–1.2%)	19	1809	0.00–6.49%
Pubovaginal	5	0.99% (0.39–1.9%)	8	696	0.00–2.63%
Return to operating room for erosion					
Burch	2	0.28% (0.04–2.03%)	1	352	0.00–0.30%
Minisling	3	1.4% (0.5–2.8%)	5	399	0.53–2.86%
Pubovaginal	5	1.6% (0.8–2.7%)	16	640	0.00–12.50%
Retropubic	12	1.9% (1.0–3.0%)	13	703	0.00–6.45%
Obturator	7	2.7% (1.5–4.3%)	14	518	0.00–8.24%
Exposure					
Burch	4	0.00% (0.02–6.22%)	0	130	0.00–0.00%
Retropubic	29	1.4% (1.1–1.7%)	84	5684	0.00–12.90%
Minisling	19	2.0% (1.5–2.6%)	61	2408	0.00–19.05%
Obturator	31	2.2% (1.7–2.7%)	66	3253	0.00–10.00%
Pubovaginal	10	5.4% (4.0–7.0%)	48	851	0.00–15.52%
Wound infection					
Minisling	3	0.31% (0.05–0.80%)	2	852	0.00–1.04%
Obturator	14	0.74% (0.43–1.1%)	14	2348	0.00–2.11%

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(continued)

TABLE 3

Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies^{1,9-57,59-117} (continued)

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Retropubic	13	0.75% (0.54–0.98%)	43	5781	0.00–13.04%
Pubovaginal	3	2.6% (0.8–5.4%)	4	174	0.85–5.56%
Burch	5	7.0% (4.3–10%)	17	269	3.13–9.68%
Urinary tract infection					
Minisling	13	3.6% (2.8–4.6%)	72	1762	0.74–18.33%
Pubovaginal	4	4.2% (2.5–6.3%)	21	420	1.84–18.75%
Obturator	21	4.3% (3.4–5.2%)	88	1826	0.00–16.79%
Burch	7	5.9% (4.2–7.9%)	55	648	0.00–31.51%
Retropubic	21	11.0% (9.7–11%)	718	6286	0.00–23.33%
Bowel injury					
Obturator	5	0.00% (0.00–1.96%)	0	410	0.00–0.00%
Retropubic	7	0.34% (0.09–1.36%)	2	594	0.00–1.57%
Minisling	1	0.74% (0.10–5.30%)	1	136	0.74–0.74%
Burch	1	3.13% (0.44–23.63%)	1	32	3.13–3.13%
Nerve injury					
Minisling	1	0.00% (0.02–5.95%)	0	136	0.00–0.00%
Retropubic	4	0.06% (0.01–0.43%)	1	1642	0.00–0.07%
Obturator	3	0.61% (0.09–4.36%)	1	165	0.00–1.72%
Ureteral injury					
Retropubic	1	0.00% (0.00–9.25%)	0	88	0.00–0.00%
Pubovaginal	4	0.18% (0.03–1.26%)	1	567	0.00–1.28%
Burch	1	0.61% (0.15–2.46%)	2	329	0.61–0.61%
Obturator	1	1.22% (0.17–8.87%)	1	82	1.22–1.22%
Vascular injury					
Obturator	2	0.00% (0.00–6.75%)	0	120	0.00–0.00%
Retropubic	4	0.08% (0.04–0.18%)	6	7149	0.00–0.09%
Overactive bladder/urgency					
Burch	3	4.3% (2.5–6.5%)	17	387	2.86–21.74%
Obturator	8	5.3% (4.2–6.5%)	106	1485	0.00–34.53%
Minisling	11	5.4% (4.4–6.5%)	103	1769	2.22–21.00%
Retropubic	15	6.9% (6.0–7.7%)	374	3486	0.76–45.00%
Pubovaginal	5	8.6% (6.5–11%)	55	558	3.37–38.10%
Retention lasting <6 wk postoperatively					
Minisling	13	2.1% (1.5–2.8%)	36	1778	0.00–5.88%
Obturator	17	2.3% (1.8–3.0%)	70	2629	0.00–10.00%
Retropubic	18	3.1% (2.7–3.5%)	248	7127	0.00–21.74%

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(continued)

TABLE 3

Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies^{1,9-57,59-117} (continued)

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Pubovaginal	10	12% (10.2–14%)	158	1053	3.03–81.97%
Burch	5	17% (13–21%)	55	288	0.00–32.88%
Retention lasting >6 wk postoperatively					
Obturator	6	2.4% (1.4–3.6%)	70	2629	0.00–10.00%
Retropubic	9	2.7% (2.1–3.4%)	248	7127	0.00–21.74%
Minisling	2	3.3% (1.6–5.7%)	36	1778	0.00–5.88%
Pubovaginal	6	7.5% (5.4–10%)	158	1053	3.03–81.97%
Burch	4	7.6% (4.7–11%)	55	288	0.00–32.88%
Return to operating room for urinary retention					
Burch	4	0.00% (0.00–1.54%)	0	522	0.00–0.00%
Obturator	22	1.1% (0.7–1.5%)	23	2342	0.00–6.67%
Retropubic	21	1.2% (0.9–1.7%)	48	3103	0.00–24.00%
Minisling	12	1.9% (1.2–2.9%)	16	970	0.00–5.00%
Pubovaginal	15	3.0% (2.3–3.9%)	57	1667	0.00–7.69%
Groin pain					
Pubovaginal	2	0.34% (0.09–1.36%)	2	591	0.00–0.61%
Minisling	12	0.62% (0.30–1.1%)	14	1619	0.00–5.26%
Burch	2	1.10% (0.42–2.98%)	4	364	0.00–11.43%
Retropubic	12	1.5% (1.0–2.1%)	29	1811	0.00–5.56%
Obturator	17	6.5% (5.3–7.7%)	128	1594	0.00–36.67%
Leg pain					
Retropubic	4	0.62% (0.16–2.51%)	2	322	0.00–1.69%
Minisling	4	1.6% (0.5–3.2%)	4	337	0.00–2.63%
Obturator	7	16% (13–19%)	112	649	3.66–60.87%
Bladder perforation					
Obturator	32	0.70% (0.46–0.98%)	22	4000	0.00–4.76%
Minisling	6	0.85% (0.40–1.5%)	12	1138	0.00–4.41%
Pubovaginal	14	2.3% (1.5–3.3%)	23	1069	0.00–5.56%
Burch	10	2.8% (1.7–4.1%)	19	753	0.00–6.25%
Retropubic	41	3.6% (3.3–3.9%)	420	11,390	0.00–24.39%
Urethral perforation					
Burch	1	0.00% (0.00–34.04%)	0	25	0.00–0.00%
Obturator	7	0.20% (0.05–0.80%)	2	1013	0.00–1.72%
Retropubic	8	0.41% (0.19–0.72%)	17	2211	0.00–5.37%
Minisling	1	2.70% (0.38–20.26%)	1	37	2.70–2.70%

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(continued)

TABLE 3

Rates of AEs by sling type analyzed from randomized controlled trials and included AE studies^{1,9-57,59-117} (continued)

Sling category	Studies	Summary estimate of incidence (95% CI)	Events	Total n	Range of AE proportions across studies
Vaginal perforation					
Pubovaginal	1	0.00% (0.00–2.46%)	0	326	0.00–0.00%
Burch	2	0.21% (0.03–1.50%)	1	475	0.00–0.30%
Retropubic	12	0.73% (0.40–1.2%)	19	1892	0.00–15.00%
Minisling	10	1.3% (0.8–1.9%)	20	1538	0.00–4.84%
Obturator	20	2.8% (2.2–3.5%)	82	2498	0.00–10.87%
Deep vein thrombosis					
Obturator	2	0.00% (0.00–12.03%)	0	68	0.00–0.00%
Retropubic	3	0.06% (0.01–0.43%)	1	1660	0.00–0.07%
Pubovaginal	4	0.35% (0.09–1.42%)	2	567	0.00–1.28%
Burch	3	0.58% (0.11–1.4%)	4	506	0.00–3.23%

AE, adverse event; CI, confidence interval.

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quality based on the likelihood of biases and completeness of reporting. Grades for different outcomes could vary within the same study.

Data synthesis and analysis

We were able to identify comparisons for MUS vs Burch, pubovaginal slings vs Burch, pubovaginal slings vs MUS, retropubic MUS vs obturator MUS, retropubic MUS vs retropubic MUS (based on route of passage), obturator MUS vs obturator MUS (based on route of passage), and minisling vs other sling. When at least 3 RCTs compared the same surgeries for the same outcomes and provided adequate data for metaanalysis (including for AEs), we performed random effects model metaanalyses to estimate pooled odds ratios (ORs). We included data from the time point closest to 12 months' follow-up that were reported. For objective cure, studies used cough stress test, pad test, or both methods. Across studies, we treated the different methods as equivalent (ie, we included both methods in the metaanalyses), but when a single study reported both methods, we preferentially chose stress test over pad test or a combined outcome (both pad and stress tests). When at least 3 studies (pre-post,

nonrandomized comparative, or RCT) reported the same AE for the same sling type, we performed random effects model metaanalyses of the arcsine transformed proportion of women with the outcome.⁶ The arcsine transformed proportion was used to minimize bias due to the nonnormal distribution when proportions are close to 0. However, when the total number of events was <3 or metaanalysis gave an implausible summary estimate, the exact proportion and confidence interval (CI) were calculated for the total number of events and women at risk.⁷ These absolute rates of AEs are compared qualitatively between procedures, and all data are presented in Table 3.

For each comparison of different sling types (or vs Burch), we generated an evidence profile by grading the quality of evidence for each outcome according to the Grades for Recommendation, Assessment, Development, and Evaluation system. The process considered the methodological quality, consistency of results across studies, directness of the evidence, and imprecision or sparseness of evidence to determine an overall quality of evidence. Four quality rating categories were possible: high (A), moderate (B), low (C), and very

low/insufficient (D).⁸ Evidence profiles for the reviewed studies are in the Appendix.

We developed clinical practice guideline statements incorporating the balance between benefits and harms of the compared interventions when the data were sufficient to support these statements. Each guideline statement was assigned an overall level of strength of the recommendation (1 = strong, 2 = weak) based on the quality of the supporting evidence and the size of the net benefit. The strength of a recommendation indicates the extent to which one can be confident that adherence to the recommendation will do more good than harm. The wording and its implications for patients, physicians, and policymakers are detailed in Table 4.

We presented our findings at the 39th Annual Scientific Meeting of the Society of Gynecologic Surgeons in April 2013 in Charleston, SC. A link to the guidelines and manuscript was then e-mailed to the entire membership for review and vetting in August 2013 prior to submission for publication.

RESULTS

The MEDLINE search identified 2849 abstracts, of which we retrieved 881

TABLE 4

Society for Gynecologic Surgeons Systematic Review Group sling surgery for stress urinary incontinence in women, clinical practice guidelines**Midurethral sling vs Burch (open or laparoscopic)**

For women considering midurethral slings or Burch procedures for treatment of SUI, we suggest either intervention for objective and subjective cure and that decision be based on: (1) which adverse events are of greatest concern to patient; and (2) any other planned concomitant surgeries (vaginal vs abdominal route). (1A)

- Midurethral slings may result in lower rates of perioperative adverse events such as blood loss, postoperative pain, operating room time, hospital stay, bowel injury, wound infection, and hematomas. (1C)
- Burch procedures may result in lower rates of return to operating room for retention, erosion, overactive bladder symptoms, and groin pain. (1C)

Pubovaginal sling vs Burch

For women considering pubovaginal slings or Burch procedures for treatment of SUI, we recommend pubovaginal slings to maximize cure outcomes. (1A)

- Burch procedure results in lower rates of erosion, overactive bladder symptoms, and retention requiring reoperation. (1C)
- Pubovaginal slings result in lower rates of wound infection, bladder/vaginal perforation, and bowel injury. (1C)

Pubovaginal sling (biologic and synthetic) vs midurethral sling (only TVT was studied)

For women considering pubovaginal or midurethral sling for treatment of SUI, we recommend midurethral sling for better subjective cure outcomes. (2C)

- Midurethral slings may result in lower rates of perioperative outcomes such as operating room time, blood loss, and hospital stay. (2D)
- Pubovaginal slings may result in lower rates of adverse events such as urinary tract infection and vaginal perforation. (2D)

Retropubic vs obturator midurethral slings

For women considering retropubic or transobturator midurethral sling, we recommend either intervention for objective and subjective cure and that decision be based on which adverse events are of greatest concern to patient. (1A)

- Retropubic slings result in lower rates of sling erosion, need to return to operating room for treatment of sling erosion, groin/leg pain, and vaginal perforation. (1D)
- Transobturator midurethral slings result in shorter operative time, fewer bladder/urethral perforations, less perioperative pain, fewer urinary tract infections, and less overactive bladder symptoms. (1D)

Obturator vs obturator or retropubic vs retropubic midurethral slings

There is insufficient evidence to provide recommendation for choosing among specific obturator or retropubic slings.

Minisling (TVT-Secur U/H position and MiniArc studied) vs other sling (TVT and TVT-O studied)

For women considering minislings (specifically TVT-Secur in H or U configuration) compared to traditional midurethral slings for treatment of SUI, we recommend traditional midurethral sling to maximize cure rates. (1A)

- Route of traditional midurethral sling that would be performed is important consideration in regard to adverse events compared with minislings. For example, minislings have similar rates of postoperative overactive bladder symptoms compared with obturator slings, but lower rates compared with retropubic slings. Exposure of sling postoperatively is similar between obturator slings and minislings, but retropubic slings have lower rates than both other types. (1D)
- Dyspareunia is more common with minisling than either retropubic or obturator sling, but absolute rates are low for all types of slings. (1D)

MiniArc; AMS, Minnetonka, MN; TVT-O; Ethicon Gynecare, Cincinnati, OH; TVT-Secur; Ethicon Gynecare.

SUI, stress urinary incontinence; TVT, tension-free vaginal tape; TVT-O, tension-free vaginal tape obturator.

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full-text papers that were further assessed in detail (Figure 1). This process resulted in 127 papers detailing RCTs (Table 1), from which there were 49 unique, eligible trials. There were also 704 additional papers reflecting other study designs, which were considered for AE data (Table 3). After limiting the non-RCT papers to those with the largest number of patients, we included 39 of those studies in addition to collecting AE information from RCTs (Table 3).

We categorized the trials into 6 comparisons, which are discussed in detail below and in Table 1.

MUS vs Burch urethropexy

There were 10 RCTs for this comparison with overall moderate quality of evidence (Supplementary Table 1).⁹⁻¹⁸ Two studies examined obturator MUS,^{10,15} while the remaining analyzed a retropubic sling vs Burch urethropexy, which was performed via laparotomy except in 3 studies that analyzed laparoscopic

Burch surgery.^{11,13,14} There were no studies comparing minislings to Burch urethropexy.

The evidence reviewed did not support a difference between the 2 surgeries with regard to objective cure, subjective cure, quality-of-life, or sexual function outcomes. While 8 studies provided data about cure outcomes, there were fewer studies evaluating quality of life^{13,16,18} and sexual function.¹⁸

Metaanalysis of objective cure did not show a significant difference for sling